US005947910A

United States Patent [19]

Zimmet

[11] Patent Number: 5,947,910

[45] Date of Patent: Sep. 7, 1999

[54] **EXTRAVASATION DETECTION TECHNIQUE**

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[21] Appl. No.: **08/980,094**

[22] Filed: **Nov. 26, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/957,121, Oct. 24, 1997, which is a continuation-in-part of application No. 08/924,631, Sep. 5, 1997, abandoned, which is a continuation of application No. 08/491,149, Jun. 16, 1995, abandoned, which is a continuation of application No. 08/323,595, Oct. 17, 1994, abandoned, which is a continuation-in-part of application No. 08/182,221, Jan. 14, 1994, abandoned.

[51] **Int. Cl.**[6] **A61B 5/05**

[52] **U.S. Cl.** **600/547**; 604/50; 604/51; 604/66

[58] **Field of Search** 600/547; 604/50, 604/51, 65, 66, 67, 245; 340/573; 128/DIG. 13

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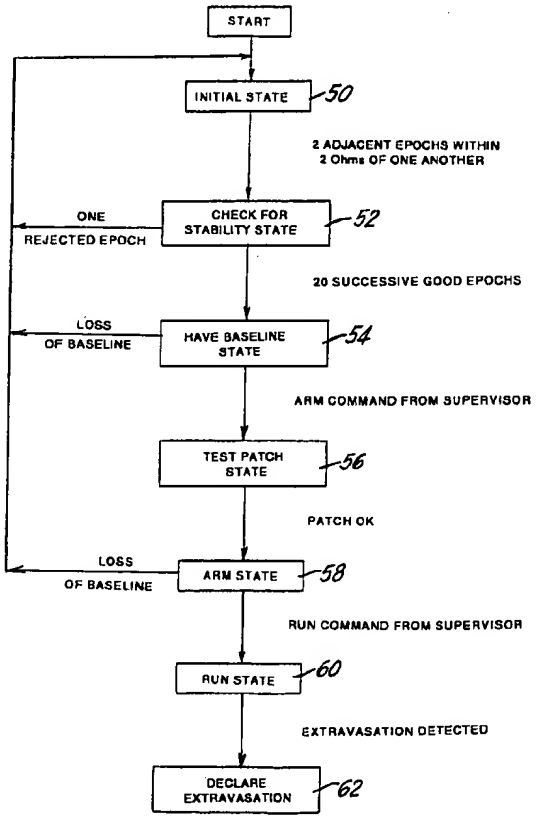
[57] **ABSTRACT**

The technique for detecting extravasation during the injection of fluid into a patient involves the establishment of a baseline representing impedance at the zone of the injection prior to the injection starting. Extravasation is signaled when at least two characteristics appear. First is that the impedance varies from the baseline more than a predetermined amount in more than a predetermined number of discreet time slots called epochs herein. Second is that, the rate of change of the impedance, which is called the slope herein, is consistently greater than a predetermined amount.

22 Claims, 4 Drawing Sheets



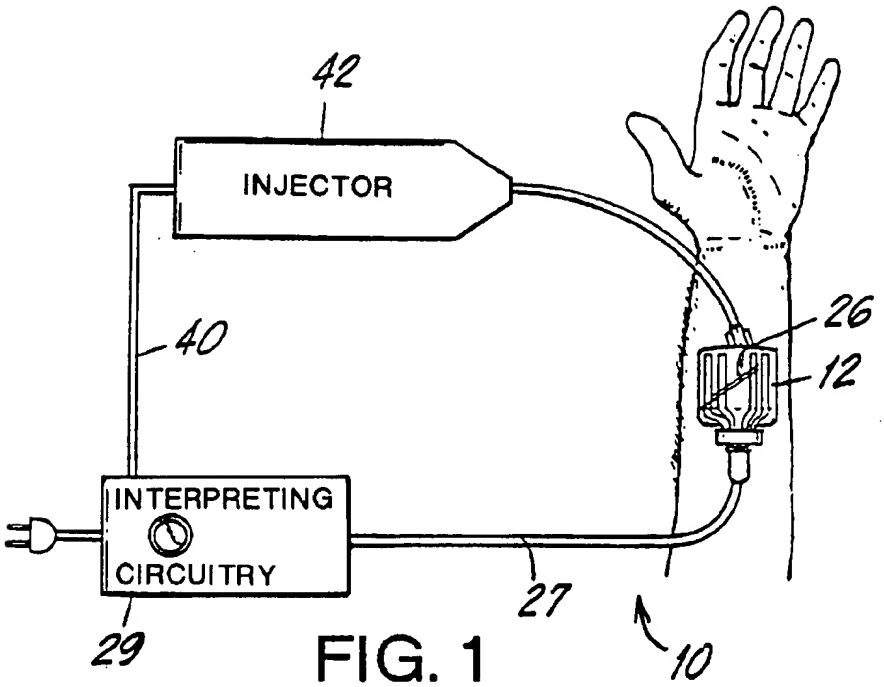

42
INJECTOR
40
26
12
INTERPRETING
CIRCUITRY
29
27
10

FIG. 1

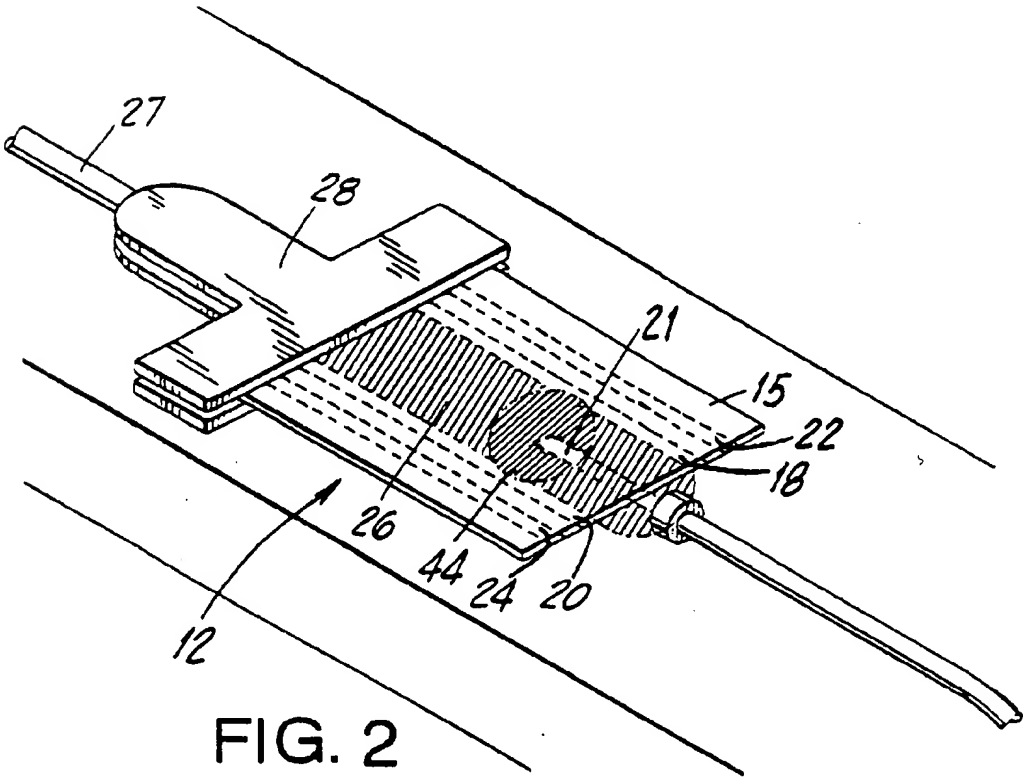

27
28
21
15
22
18
26
44
24
20
12

FIG. 2

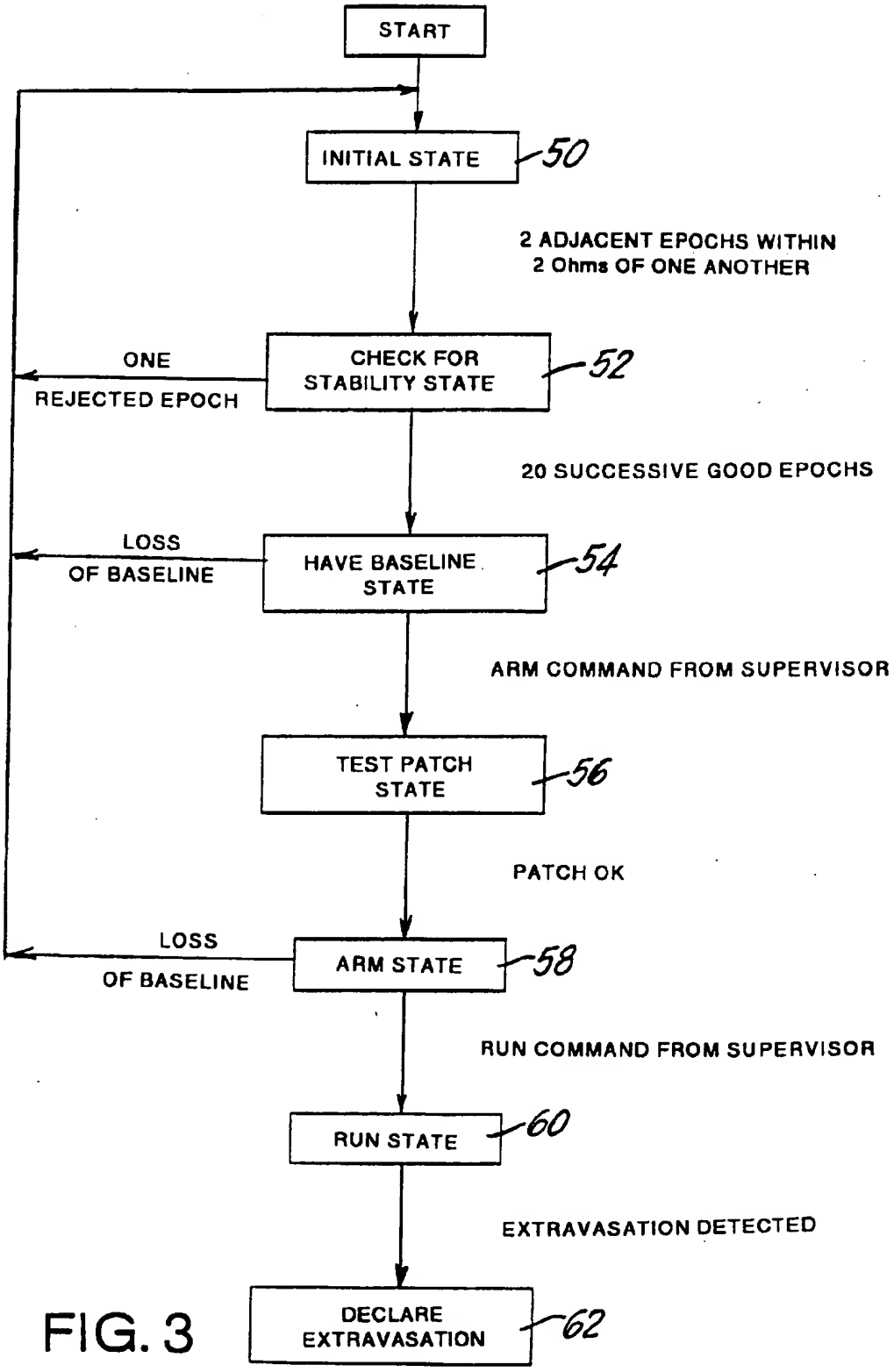

START
INITIAL STATE
50
2 ADJACENT EPOCHS WITHIN
2 Ohms OF ONE ANOTHER
ONE
REJECTED EPOCH
CHECK FOR
STABILITY STATE
52
20 SUCCESSIVE GOOD EPOCHS
LOSS
OF BASELINE
HAVE BASELINE
STATE
54
ARM COMMAND FROM SUPERVISOR
TEST PATCH
STATE
56
PATCH OK
LOSS
OF BASELINE
ARM STATE
58
RUN COMMAND FROM SUPERVISOR
RUN STATE
60
EXTRAVASATION DETECTED
DECLARE
EXTRAVASATION
62

FIG. 3

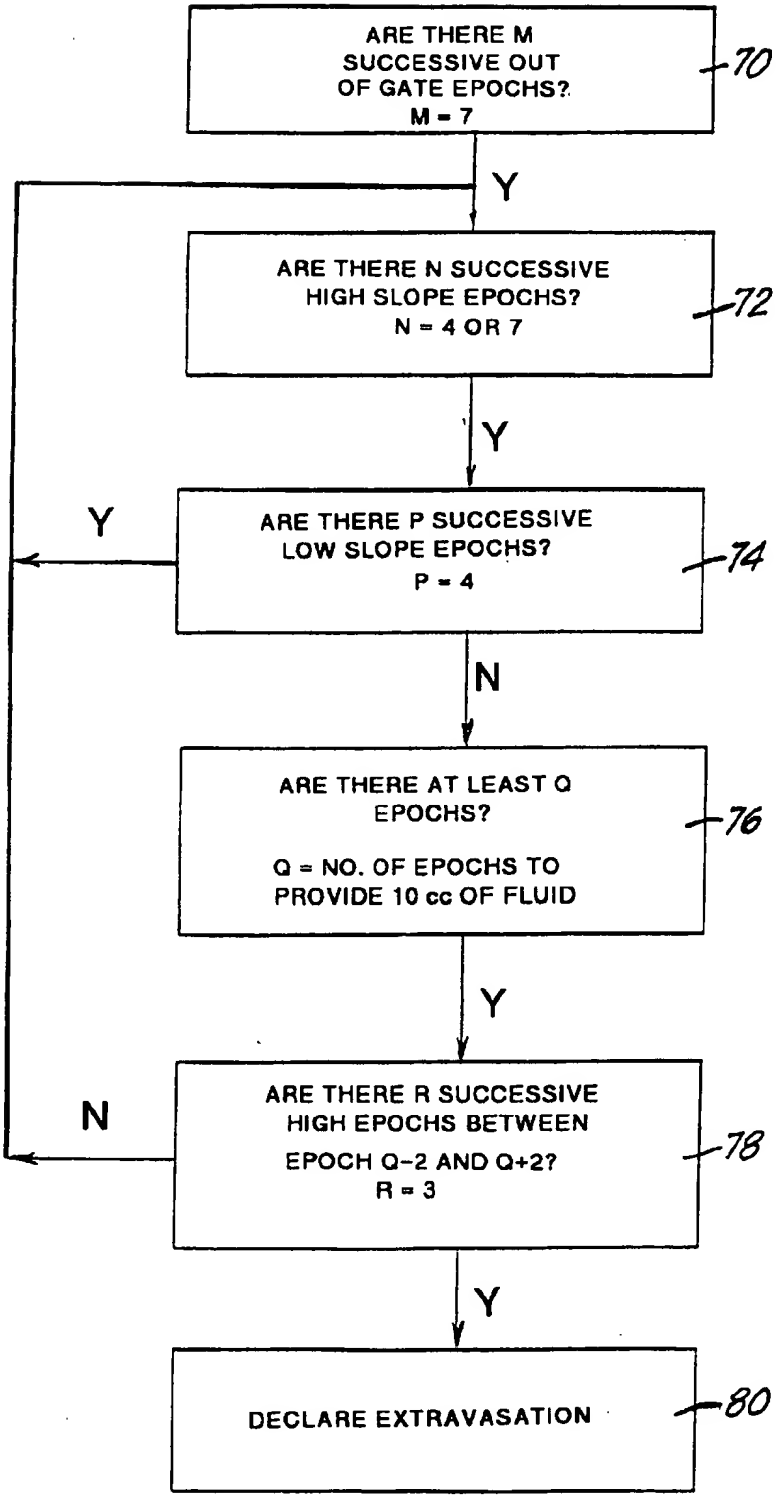

ARE THERE M SUCCESSIVE OUT OF GATE EPOCHS? M = 7
70
Y
ARE THERE N SUCCESSIVE HIGH SLOPE EPOCHS? N = 4 OR 7
72
Y
Y
ARE THERE P SUCCESSIVE LOW SLOPE EPOCHS? P = 4
74
N
ARE THERE AT LEAST Q EPOCHS?
Q = NO. OF EPOCHS TO PROVIDE 10 cc OF FLUID
76
Y
N
ARE THERE R SUCCESSIVE HIGH EPOCHS BETWEEN EPOCH Q-2 AND Q+2? R = 3
78
Y
DECLARE EXTRAVASATION
80

FIG. 4

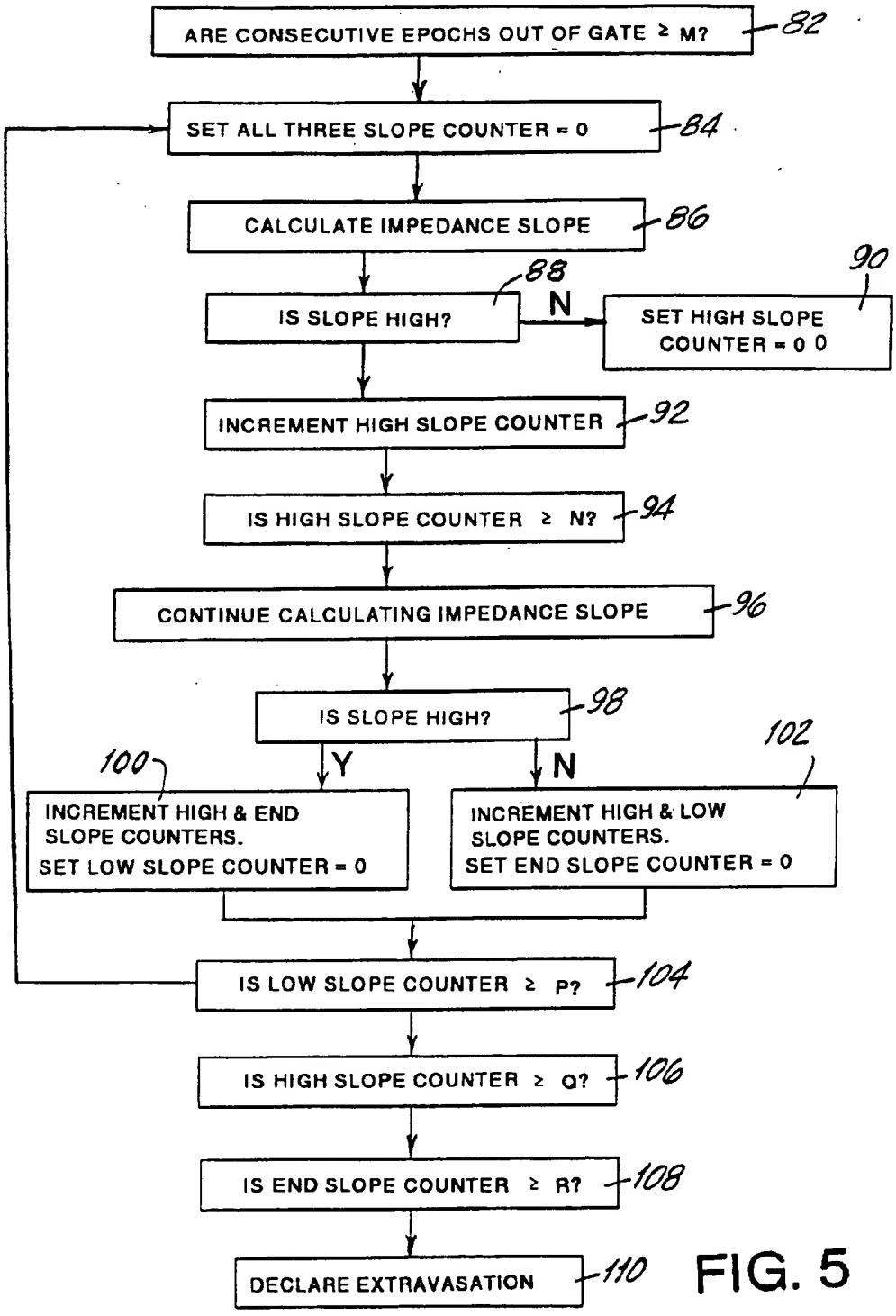

ARE CONSECUTIVE EPOCHS OUT OF GATE ≥ M?
82
SET ALL THREE SLOPE COUNTER = 0
84
CALCULATE IMPEDANCE SLOPE
86
IS SLOPE HIGH?
88
N
SET HIGH SLOPE COUNTER = 0 0
90
INCREMENT HIGH SLOPE COUNTER
92
IS HIGH SLOPE COUNTER ≥ N?
94
CONTINUE CALCULATING IMPEDANCE SLOPE
96
IS SLOPE HIGH?
98
Y
N
100
INCREMENT HIGH & END SLOPE COUNTERS.
SET LOW SLOPE COUNTER = 0
102
INCREMENT HIGH & LOW SLOPE COUNTERS.
SET END SLOPE COUNTER = 0
IS LOW SLOPE COUNTER ≥ P?
104
IS HIGH SLOPE COUNTER ≥ Q?
106
IS END SLOPE COUNTER ≥ R?
108
DECLARE EXTRAVASATION
110

FIG. 5

EXTRAVASATION DETECTION TECHNIQUE

REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 08/957,121 filed on Oct. 24, 1997 titled: Extravasation Detection, which is a continuation-in-part of application Ser. No. 08/924,631 filed Sep. 5, 1997, now abandoned, which is a continuation of application Ser. No. 08/491,149 filed on Jun. 16, 1995, now abandoned, which in turn is a continuation of application Ser. No. 08/323,595 filed on Oct. 17, 1994, now abandoned, which in turn is a continuation-in-part of application Ser. No. 08/182,221 filed on Jan. 14, 1994 now abandoned; all of which are titled: Extravasation Detection System.

Further details of the patch which is employed in a preferred embodiment of this invention are disclosed in said application filed on Oct. 24, 1997 entitled: Extravasation Detection. The contents of said Oct. 24, 1997 application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to a device and method for the detection of extravasation and more particularly to the detection of extravasation of ionic and non-ionic contrast media.

Extravasation or infiltration is a complication related to the use of power injectors during contrast fluid media injection procedures. When an extravasation occurs, contrast is injected into the tissue surrounding the blood vessel, instead of into the blood vessel itself. The causes for extravasation vary, ranging from operator error in placement of the needle to physiological limitations of the blood vessel to tolerate the rate of fluid administration.

Complications related to extravasation may be quite severe and may include tissue necrosis. This may require reconstructive surgery to repair.

Presently, the only method for detecting an extravasation is for the operator to visually observe it. However, by the time an extravasation is visually observable, much of the previously discussed damage may have occurred.

Accordingly, it is an object of the present invention to provide a safe, efficient, inexpensive and reliable means for the early detection of extravasations.

A very large number of contrast media injection procedures are undertaken each year in the United States; something in the order of ten million. Less than 0.2% of these procedures result in an extravasation. Yet the absolute number is substantial because the base number is so large. The occurrence of an extravasation requires that the procedure be terminated and reinstituted. Accordingly, in a normal situation where an extravasation occurs, early detection is important from the point of view of minimizing the impact on the patient, saving time and providing a timely reinstitution of the procedure.

Although extravasation is not life-threatening, when it does occur it causes discomfort to the patient. It requires a great deal of attention from the doctor and usually means that a procedure has to be interrupted. Thus, it is important that any extravasation detection technique avoid a false indication of extravasation.

In relatively rare cases the extravasation can be quite harmful to the patient. Therefore early detection will avoid patient trauma or other injury.

The false detection of an extravasation results in terminating a procedure. Starting the procedure constitutes unnecessary trauma to the patient and expense. Therefore, any detection technique that gives a noticeable number of false indications will not be used by the doctor.

Accordingly, it is important that any detection technique to be acceptable combine an extremely small number of false indications of extravasation coupled with a reasonably high specificity to the extravasation event being detected.

The relatively large number of contrast media injections undertaken coupled with the relatively small percentage of extravasations that occur means that any procedure to be acceptable to the medical profession has to be non-invasive.

It is an accepted fact that any invasive procedure carries with it risks and trauma. They are to be avoided unless the benefit trade-off warrants such.

In order for an extravasation detection technique to be acceptable in this context, it must provide next to no false indications of extravasation. A false indication would mean stopping a procedure which did not have to be stropped. Thus the technique must be specific to extravasation and non-responsive to other phenomenon such as the patient moving his or her arm.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic view of a system employing the processing of this invention.

FIG. **2** is a more detailed diagrammatic view of the patch **12** of FIG. **1** that can be used in connection with the process of this invention. The patch is shown on a patient indicating, in idealized form, the relation between an extravasation **44** and the measuring zone **26**.

FIG. **3** is a state sequence chart showing the overall method of this invention and, in particular, the various states through which processing occurs. The states prior to the Run State occur prior to the start of injection and have as one object to establish a stable impedance baseline that is then used in the Run State as the base for comparison to determine whether or not there is an extravasation.

FIG. **4** is a high level partial flow chart of the Run State of this invention showing certain conditions that have to be detected prior to the determination that there is an extravasation.

FIG. **5** is a more detailed partial flow chart showing processes that occur during the slope measurement stages of the Run State.

BRIEF DESCRIPTION

In brief, this invention involves a technique of detecting extravasation that may occur when a needle is inserted into a patient for the purpose of delivering fluid into the patient's vascular system.

At the site of the injection, a patch is applied having excitation electrodes and pick-up electrodes. A high frequency signal applied by the excitation electrodes is coupled to the pick-up electrodes through the patient's body under the patch. The value of the signal picked up by the pick-up electrodes is a function of the body impedance at the site.

A baseline impedance is determined prior to the start of injection. When fluid is injected into the vascular system, no significant change in the pick-up signal occurs. However, if there is an extravasation, the pool of fluid that collects at the site will materially change the impedance value detected.

Accordingly, a baseline impedance is established prior to the injection to represent the impedance condition at the site. Deviations from that baseline condition, if they exceed certain thresholds, are deemed to indicate an extravasation.

In the procedure involved, there are certain stages or states, prior to the injection, which are used to determine that there is sufficient stability in the impedance at the site and to determine the baseline. After these pre-injection states have determined the baseline impedance and the injection is to proceed, a Run State is initiated in which measurements of impedance value changes and rate of change (that is, slope) are determined. If during this Run State, the values of the changes in impedance, and most importantly, the values of the impedance slope are greater than certain thresholds, an indication of extravasation is given to the operator and the injection procedure can be stopped.

In order to minimize the occurrence of false-positives (false indications of extravasation), certain constraints are established on the response to the changes in impedance values from the initial baseline. One constraint is that a predetermined number of measurements have to be made that deviate past a certain threshold from the baseline. Another important requirement is that the rate of change of the impedance measurements has to exceed a certain absolute value and it has to do so on a consistent basis. During this Run State check, if certain relatively low value impedance measurements are made and certain relatively low slope measurements are made, the Run procedure resets either entirely or in part. These reset occasions are to minimize the occurrence of false-positives.

Definitions.

Certain terms used in this application have meanings which may not be evident from the literature. Other terms are best understood before reading the detailed description. The following terms are used with the following definitions. An understanding of the disclosure, as well as the scope of the claims, requires an understanding of these definitions.

Point. One hundred impedance measurements are taken every second. Each measurement is called a point. The impedance measurement is based on the amplitude of an a.c. signal induced in a pick up coil coupled to the zone on the patient where an extravasation would be manifest. An analog to digital converter provides a digital value for the impedance for analysis in an appropriately programmed microprocessor.

Epoch. An epoch is the term for a pre-determined time period. In the embodiment described, this time period is 0.2 seconds. The epoch time can be varied depending on the particular application involved and the sensitivity required. During each epoch, a number of point measurements are taken. In the embodiment described, up to twenty points are taken during each epoch.

Filter Envelope. This is an envelope used for the filtering of spikes. It is equal to plus and minus four (±4) ohms around the epoch impedance average that is calculated at the point involved.

Valid Point. A point within the filter envelope is a valid point. However, a point that is outside the filter envelope but is less than or equal to five ohms from the prior point is also a valid point.

Accepted Epoch. This is an epoch that contains eighty percent or more valid points out of the twenty points calculated during each epoch in this embodiment.

Rejected Epoch. This is an epoch that contains less than eighty percent valid points.

Base Epsilon Criteria. The base epsilon criteria is two ohms. The current epoch impedance is compared to the epoch impedance average up to that point. If the current epoch is an accepted epoch and is within the two ohm base epsilon criteria, it is deemed a good epoch. It the accepted epoch fails the base epsilon criteria, it is deemed a bad epoch.

Range. An impedance range of 40 ohms to 225 ohms has been selected to represent the range within which meaningful impedance measurements might occur. If at any time, an epoch average is outside this range, the process starts over; that is, the system resets to the Initial State.

Epoch Impedance. An impedance value is assigned to each epoch. This impedance value is based on the average of the up to twenty valid point measurements taken during each epoch. It should be noted that there is a requirement that a point be within a certain range so that if a few points are aberrational they will not be used to calculate the epoch impedance. That is, spikes are eliminated. Except for certain rejected epochs, there is an impedance value assigned to each epoch. That impedance value, although an average of a number of points, is a single value and is the basis for most of the calculations involved in this process.

Sliding Window. The epoch impedance average and epoch impedance slopes defined below are based on a plurality of epochs. Up to seventy five epochs constitute the window for determining epoch impedance average. Seven epochs are the window used for calculating epoch impedance slope values. As the latest epoch occurs, the earliest of the epochs in the window is dropped and the latest epoch included. This moving window is called a sliding window. Thus successive value calculations are based on similar sets of epochs, one epoch at a time being replaced. Thus the successive average impedance values and slope values do not change a great deal. The values are keyed to the most recent epoch in the window. But that is essentially an arbitrary matter. The point is there is a sliding window which in particular is one that is quantized in that it increments by one epoch each time it "slides".

Epoch Impedance Average (Also: Epoch Impedance Sliding Window Average). An epoch impedance average is an averaging of the point impedances of a plurality of consecutive epochs. This is distinct from the averaging of the up to twenty points which provide an epoch impedance. This epoch impedance average is based on a sliding window of epochs. Thus it is also called an Epoch Impedance Sliding Window Average. In the embodiment disclosed, it is the average of points in up to seventy-five epochs including the epoch under consideration. Thus as each epoch progresses, the sliding window drops the earliest epoch involved and adds the new epoch. Under initial conditions, this epoch impedance average will encompass less than 75 epochs. The epoch impedance average is used to provide the baseline for the Run State and in calculation of the base epsilon criteria.

The calculation of epoch impedance average is based on the valid points in the window rather than an average of the epoch impedances. In the up to seventy five epoch window, all valid points, except points in rejected epochs, are used and those points are averaged. Thus valid points in bad epochs are employed as well as valid points in good epochs. But when a rejected epoch is within the seventy-five epoch window, all of the points, including valid points, are ignored for the purpose of calculating epoch impedance average.

Good Epoch. A good epoch is an epoch in the pre-injection stages which meets certain criteria that essentially are (a) it has 80% of its points within a range that filters out spikes and (b) it has an epoch impedance that is within two ohms of whatever epoch impedance average is calculated at that point in processing. This means that a good epoch has at least 80% valid points and passes the base epsilon test.

Bad Epoch. A bad epoch is an epoch in the pre-injection stages which, like the good epoch, has 80% of its points within the range that filters out spikes and thus is an accepted epoch. But a bad epoch fails the base epsilon test.

Run State. There are various processing stages prior to the start of fluid injection into a patient. The Run State is the stage of extravasation checking which starts at the start of fluid injection.

Baseline. The baseline is the epoch impedance sliding window average established just prior to the start of the Run State. It is used as the basis for detecting impedance deviations that may indicate an extravasation.

Impedance Gate. The impedance gate is used in the Run State. It is an impedance envelope around the epoch impedance average used as a baseline in the Run State. The purpose of the gate is to reduce the effect of noise. The gate envelope is less than the magnitude of an extravasation indicating signal. Epoch impedances outside the gate are relevant to the analysis to determine extravasation. In the embodiment disclosed the gate is ±1.33 ohms. Experience and application could vary the magnitude of the gate.

Epoch Impedance Slope (Also: Impedance Slope.). An epoch impedance slope is a value for the rate of change in impedance over a plurality of consecutive epochs. It is used in the Run State only. The slope is based on a sliding window of epochs. In this embodiment, an algebraic best-fit line using the least squares method is established for a sliding window of seven epoch impedances. The value of that slope is keyed to the last epoch in the window.

High Slope. When in the Run State, if the epoch impedance slope is consistently high, that is a sign there is an extravasation. In this embodiment, a high slope is one that is greater than plus 0.5 (+0.5) ohms per second or less than minus 0.5 (−0.5) ohms per second. The plus threshold is for non-ionic media. The minus threshold is for ionic media. The High Slope Counter counts these slopes.

Low Slope. An epoch impedance slope that is not a high slope is a low slope. Thus any slope between minus five and plus five is a low slope. A low slope increments the Low Slope Counter.

Gate Threshold. In the Run State, a gate of +1.33 ohm is set around the baseline impedance provided by the Have Baseline and Arm States. In order to initiate a detection of extravasation, a predetermined number of consecutive epoch impedances outside the gate must be detected in the Run State.

In this embodiment, that threshold number is seven (7) consecutive epochs having impedance outside the +1.33 ohm gate. An epoch average within the gate at any point during the Run State resets the gate threshold counter and all slope counters thereby restarting the Run State calculation.

High Slope Threshold. Once the gate threshold of seven has been met, epoch impedance slopes are calculated and counted. A threshold of a predetermined number of consecutive epoch high slope values are required immediately after seven out of gate impedances in order to advance the process toward an indication of extravasation. This threshold is seven (7) consecutive high slopes where the injection rate is low; that is, 4.0 ccs per second or less and is four (4) consecutive high slopes where the injection rate is high; that is, greater than 4.1 ccs per second.

Low Slope Reset. A low slope value in the Run State resets the High Slope Counter if the low slope value occurs during the establishment of the High Slope threshold.

After the High Slope threshold is met, then only if the Low Slope Counter equals a predetermined threshold is the High Slope Counter reset.

End Slope Check. As a final check to assure the minimization of false-positives, there is a requirement that there be three successive high slope epochs at the point where ten cc has been injected. If the three successive high slope epochs are not detected, the slope counters are reset. However, in one embodiment, these three successive high slope epochs can be any three in a five epoch band that brackets the epoch at which ten cc has been injected. There is an End Slope Counter which is used to determine these three epochs. The End Slope Counter is reset each time a low slope is detected.

False-Positive Since the purpose of this technique is to detect an extravasation, the detection is deemed a positive result. Thus, the term false-positive refers to a false indication of extravasation.

False-Negative. A false-negative simply means a failure to detect an extravasation that exists.

Reset. Counters are used to count the number of times certain events occur. For example, each time an epoch impedance is outside the impedance gate a particular counter indicates such. Another example, is that each high slope value is counted by another counter. Before the system get to the Run State (which is the point where the counters that indicate extravasation become operative), other measurements are made by counters which provide an indication that it is appropriate to go into the Run State. All these counters, those prior to the Run State and those used during the Run State, may be reset under certain conditions. The term reset is used herein to refer to the condition when one or more counters are reset to zero. This may occur before the Run State occurs because of an indication that an appropriate baseline cannot be provided. More significantly, certain counters that are used to determine extravasation will be reset when epoch impedance values or slope values are measured to be less than certain thresholds. This reset function is important to assure that the number of false positives (false indication of extravasation) are kept to a minimum and thus necessary to achieve one of the major objects of this invention.

Abort. Under certain conditions such as where there is equipment failure, the entire system is shut down. For example, if the leads to the patch which pick-up the signal break, the procedure is stopped. The term abort is used to refer to this situation. It involves the use of standard equipment test procedures. In the abort situation, the procedure stops. This differs from reset, which involves restarting some calculation or some part of the procedure.

Counters Employed.

There are six counters employed as part of the process of this invention. Four of these counters are used only in the Run State, which is the state where extravasation may be determined. Two of these counters are used in preliminary states which occur prior to the start of injection into a patient. The following is a list of counters with an indication of their function for reference to aid in reading the detailed description.

Stability Counter—Counts Good Epochs.

A. An Initial State must count two consecutive good epochs to switch to the Check for Stability State. Therefore, this counter is reset by a rejected epoch.

B. In the Check for Stability State, the stability counter must count twenty (20) consecutive good epochs to switch to the Have Baseline State. This counter is reset by either a rejected epoch or a bad epoch.

C. The Have Baseline State holds the state as long as there is a count of 75 good epochs and less than eight (8) consecutive bad epochs. Therefore the Stability Counter is reset when the Instability Counter counts eight consecutive bad epochs.

D. In the Run State this counter is not used.

Instability Counter—Counts Bad Epochs.

A. In Initial State—not used.

B. In Check For Stability State, a count of one resets the Stability Counter.

C. In Have Baseline State, a count of eight consecutive bad epochs resets the Stability Counter. The Instability Counter is reset by a good epoch.

Epochs Out Of Gate Counter.

A. Used only in Run State. Must count seven (7) consecutive out of gate epochs to initiate the High Slope Counter count of slope calculations.

B. Reset when an epoch impedance drops within the gate.

High Slope Counter.

A. Used only in Run State.

B. Counts high slopes that is, slopes greater than 0.5 ohms per second and less than 0.5 ohms per second.

C. Must count a predetermined number of consecutive high slopes before extravasation can be declared.

D. It is reset:

(i) if the Epochs Out of Gate Counter is reset,

or

(ii) a low slope is detected during the count of consecutive high slopes,

or

(iii) if the Low Slope Counter counts a predetermined consecutive number of low slopes.

Low Slope Counter.

A. Used only in Run State.

B. Counts low slopes.

C. A count of a predetermined number of consecutive low slopes resets the High Slope Counter.

D. Reset when High Slope Counter is reset.

End Slope Counter

A. Used only in Run State.

B. Counts high slopes.

C. Must have a count of three (3) consecutive high slopes for extravasation to be indicated.

D. Reset when High Slope Counter is reset.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The System.

As shown in FIGS. **1** and **2**, a patch **12** applied to the skin of a patient includes a body **15** which has an adhesive backing that adheres the patch to the skin of the patient.

The patch contains surface electrodes **18, 20, 22** and **24**. The inner electrodes **18** and **20** define a space **26** between them. The space **26** is shaped and dimensioned to permit a needle **21** to be placed thereunder. The clip **28** contains terminals which provide an energizing signal to the outer electrodes **22** and **24**. The clip **28** also contains terminals which connect to the inner electrodes **18** and **20** and that will deliver a pick up signal that is sensed by the inner electrodes **18** and **20**.

In one embodiment, each electrode has a length of about 7.6 cm and a width of about 0.5 cm. The inner electrodes **18** and **20** are spaced from one another by about 1.9 cm and the electrodes **22, 24** are spaced apart by about 3.8 cm. In that embodiment, the electrode patch **12** has a length of about 7.6 cm and a width of about five inches. When the syringe needle **21** is introduced into the patient's vasculature, a constant alternating current is applied to the two outer electrodes **22, 24**.

In one embodiment, the current used is about 200 micro amperes at 20 kilohertz. The inner electrodes **18, 20** provide a measurement of voltage potential, the magnitude of which is a function of the impedance in the tissue under the zone **26**.

The leads in the pick up electrodes **18, 20** are included in the conduit **27** and are connected to impedance monitoring and interpreting circuity **29** which provides an indication of the tissue impedance in the zone **26**. This tissue impedance is affected by an extravasation such as the extravasation shown at **44**. Ionic contrast media has a lower impedance than does tissue. Thus if ionic contrast media extravasation occurs, the effective impedance measured by the pick up electrodes **18, 20** will be less than the tissue impedance prior to extravasation. A non-ionic contrast media has a higher impedance than does the tissue and thus will cause an increase in impedance measurements during an extravasation.

When an injection is to be made, continuous calculations of tissue impedance are made both before and during the injection procedure. As explained in greater detail further on, an extravasation is deemed to have occurred if during the injection procedure the impedance change shows a fairly consistent slope of at least plus or minus five ohms per second. It is contemplated that in certain embodiments of the invention if a determination is made that an extravasation has occurred, there will be an automatic stop signal sent by conduit **40** to the injector **42** to cease the injection. Alternately, a visual or other type of warning signal can be provided so that the person administering the injection can take appropriate action.

Initial State.

The Initial State is in effect a bootstrap state. It is necessary to start the evaluation process running. The Initial State, like all of the states up to the Run State, is a process prior to the initiation of the injection into the patient.

Once the equipment has been powered up and has been self tested by whatever routines are deemed to be appropriate so that the procedure can be started, resistance point readings are taken at the rate of twenty readings per 0.2 second duration epoch. The first epoch in the Initial State is established when at least eighty percent of the twenty consecutive points are within the predetermined impedance range of 40 ohms to 225 ohms. This 40 ohm to 225 ohm impedance range has been experimentally determined to be a range that will encompass almost every patient.

Once a first epoch has been so established, its impedance average is determined.

The next epoch is tested and determined to be an acceptable Initial State epoch if two criteria are met. The two criteria are: (1) eighty percent of its points are within a filter envelope and (2) it passes the base epsilon criteria. The filter envelope is set, in this embodiment, at plus or minus four ohms around the first epoch's impedance average. The filter is effective to eliminate spikes. The base epsilon criteria means that the epoch average of the second epoch must be within two ohms of the epoch average of the first epoch. If the second epoch does not meet these two criteria, then it is deemed to be a rejected epoch. A rejected epoch will cause a reset to the Initial State so that the testing of first and second epochs as described above will reoccur.

When two adjacent accepted epochs within the base epsilon criteria of one another have been determined, then the process is promoted to the next state which is the Check For Stability State.

Check For Stability State.

When the Initial State has been successfully processed, the processing routine moves to the Check For Stability State.

The Check For Stability State is successfully processed when twenty consecutive good epochs are detected. The Stability Counter provides this count.

A good epoch is different from an accepted epoch in that it must not only meet the criteria for an accepted epoch, but it must also meet the base epsilon criteria.

The first of the twenty epochs in the Check For Stability State also has to pass the base epsilon criteria and the immediately preceding epoch (which is the second of the two adjacent accepted epochs in the Initial State) is used to provide the average for the base epsilon ±2 ohm test for the first of the Check For Stability State epochs.

Since twenty consecutive good epochs are required to successfully go through the Check For Stability State, any accepted epoch that is not a good epoch is deemed a bad epoch and it resets the Stability Counter.

However, if at any time a rejected epoch (that is one containing fewer than eighty percent valid points out of the twenty points) is detected, then the entire processing is reset and the Initial State has to be successfully processed again.

Have Baseline State.

If the procedure has successfully processed through the Check For Stability State, it enters the Have Baseline State.

Although certain events can occur, as described below, which will cause the procedure to go back to the Reset State, the Have Baseline State is in part a waiting state. An epoch impedance baseline is determined for use in the Run State. The operator starts the Run State when an injection is to be started.

A sliding window of up to 75 epochs (covering fifteen seconds) is reviewed. The 75 epoch window is used to provide an average impedance based on valid points in the window. That average is the baseline employed during the Run State.

The valid points of all accepted epochs are included in the up to 75 epoch sliding window and the points in rejected epochs are ignored.

There is an Instability Counter which is incremented each time a rejected epoch and each time a bad epoch is detected. The rejected epoch fails the eighty percent valid point criteria and the bad epoch is an accepted epoch that fails the base epsilon criteria. When the Instability Counter indicates eight successive epochs that are not good epochs, this is an indication that the baseline has been lost and the whole system resets to the Initial State. Thus, every time a good epoch is detected (that is an accepted epoch which meets the base epsilon criteria), the Instability Counter is reset to zero. Since the good epoch is also an accepted epoch it is included in the sliding window.

The filter envelope is used to filter out spikes. It is equal to plus and minus four ohms about the average. It changes as the window average changes. It must be kept in mind that until 75 epochs do appear in the window, the points involved in the average will be from less than 75 epochs.

In addition to the filter envelope, there is a gate envelope which although not used in the Have Baseline State is calculated because it is used in connection with the subsequent Run State. This gate envelope is equal to the average epoch impedance in the window plus and minus 1.33 ohms in the embodiment involved.

The Have Baseline State does not terminate because of anything that occurs within the state (except for reset when the number of consecutive bad/rejected epochs exceeds eight) but continues until the next state is called for. The next state is called for only when the operator is ready to proceed.

Test Patch And Arm States.

If during the Baseline State, the operator is ready to proceed, the operator executes an arm command, usually by pressing an appropriate button. This arm command causes a test of the patch to be made to determine essentially that the leads to and from the patch have continuity. If this test fails, then the system aborts and the subsequent procedure is not undertaken because it is not available. However, if the test patch checks out, the system enters into the Arm State which is essentially like the Have Baseline State. An up to 75 epoch window average epoch impedance measurement is continued to provide the baseline to be employed during the succeeding Run State. In the Arm State, if an epoch average is outside the 40 ohm to 225 ohm range, the system resets to the Initial State.

When an injection is to be started and the Run command is provided from the operator, the next state, namely the Run State, is initiated.

Summary of Pre-Injection States.

With the above disclosure in mind, FIG. **3** provides a useful summary thereof. As shown in FIG. **3**, the Initial State **50** is exited when there are two adjacent epochs that meet the criteria that include the base epsilon criteria. The Check For Stability State **52** is exited to the next state when there are twenty successive good epochs. However, one rejected epoch sends the system back to the Initial State **50**. The baseline provided by the Have Baseline State **54** is the baseline described above as the epoch impedance average over up to 75 epochs. However, if there is a loss of baseline, which means eight successive bad/rejected epochs, then the system goes back to the Initial State. The Have Baseline State is exited to the next state when an arm command is received from the supervisor.

When the Arm command is received, the patch is tested as indicated at Test State **56**. If the patch test continuity shows that it is okay, then the system proceeds to the Arm State which essentially is a continuation of the Have Baseline State. Again, if there is a loss of baseline, the system goes back to the Initial State. Once the run command is received from the supervisor, the system goes into the Run State **60** and an extravasation is declared at step **62** if the Run State so detects. The description of the Run State is set forth in greater detail on the following pages.

It should be noted in connection with this system shown in FIG. **3** that hardware checks are regularly made. If there is a hardware failure including a failure of the test patch continuity, the whole system aborts and none of the processing in FIG. **3** is undertaken. In addition, the system can be reset to the Initial State if a stop command is received from the supervisor at any stage of the processing.

Run State.

The Run State is the state within which extravasation, if there is one, is detected. The Run State starts at the beginning of the injection of the patient and is in response to the operator pressing a button that simultaneously initiates the Run State and the start of injection into the patient.

In the Run State, a consistent impedance change (slope) greater than a predetermined value is used to signal an extravasation. In the embodiment disclosed, a slope greater or less than 0.5 ohms per second must be consistently measured in order to indicate extravasation.

To minimize the risk of having a false signaling of extravasation, a gate is established around the baseline. The magnitude of that gate is based on experience. Only if the epoch impedance value is outside that gate is the slope criteria reviewed for the purpose of establishing an indication of extravasation. Indeed, in the preferred embodiment if even one epoch impedance falls within the gate, the Run State is reset and all the counters which count slope are reset to zero.

Thus, in this embodiment, there must be a consistent epoch impedance value outside of the gate and the epoch impedance slope must be consistently greater than a particular criteria. Both consistent high magnitude of impedance and consistent high rate of change of impedance are

required to signal extravasation so as to assure a minimum risk of false signaling.

The following procedure explains in detail what is shown schematically in the logic flow diagrams of FIGS. **4** and **5**.

Each epoch average is calculated and a determination is made if it is an accepted epoch. If it is a rejected epoch, it is ignored. If it is an accepted epoch then a determination is made as to whether or not it is within a gate of plus or minus 1.33 ohms about the baseline received from the previous state.

If an epoch average is outside of the gate, it increments an Epochs Out Counter. Seven consecutive outside of gate epoch averages are required before the system goes into the slope calculation. Thus each time the current epoch average is within the gate, the Epochs Out Counter is reset.

After the Epochs Out Counter provides a count of seven, the slope calculation is initiated. In the slope calculation, each individual epoch average that is outside the gate is stored in a slope sliding window. The slope sliding window covers seven epochs. The first slope calculation is based on the seven consecutive out of gate epochs that are a prerequisite to this slope calculation step.

A slope is calculated based on the slope of seven consecutive epochs. If that slope is greater or less than a particular threshold (plus and minus 0.5 ohms per second in one embodiment), it is a high slope and a High Slope Counter is incremented.

The value of the slope is calculated from a best fit line using the least square method employing the epoch averages of each of seven consecutive epochs which are contained in the slope sliding window.

A Low Slope Counter is employed to count each slope that is within the ±0.5 ohm per second band. Its function is described below.

Once slope calculations start, they can be considered to operate in three phrases.

The first phase extends until the High Slope Counter indicates a predetermined number of consecutive high slope epochs. The predetermined number is a function of flow rate; seven at flow rates 4.0 cc/sec and less and four at flow rates 4.1 cc/sec and more. If even one epoch during the first phase is a low slope epoch, the High Slope Counter is reset. If the High Slope Counter counts to seven without being reset, the slope calculations enter into the second phase. It should be noted that the first high slope epoch calculation is made on the seventh of the seven successive out of gate epochs because the slope sliding window which encompasses that epoch and the preceding six epochs is operative.

In the second phase, the High Slope Counter is not reset by a low slope. During the second phase, a Low Slope Counter is also employed to count the number of low slopes that occur. If the number of consecutive low slopes equal a threshold then the High Slope Counter is reset and the first phase must be repeated. The low slope threshold is four.

Thus during the second phase if the number of consecutive low slope epochs exceeds a threshold, the slope calculation routine starts over. The low slope threshold does not put the system back to the start of the Run State.

What does put the system back to the start of the Run State is if any individual epoch impedance drops to within the gate. When that occurs, during the slope calculations, whether it is in the first, second or third phase of slope calculations, the Run State as such is reset and the Run State calculations start over including the requirement that there be the seven consecutive out of gate epochs.

In the second phase, assuming that the threshold number of consecutive low slope epochs does not occur, the High Slope Counter counts each epoch, whether it be a high slope or a low slope in order to provide a record of how many epochs have transpired. The technique requires that ten cc of fluid be injected before an extravasation can be declared. Thus there has to be at least Q epochs, representing when ten cc of fluid have been injected, as one of the criteria for an extravasation to be declared.

If the second phase of slope calculation has been completed, which means that there has been no reset of the High Slope counter and no reset of the Out Of Gate counter, the system proceeds to the third and final phase.

In the third phase, there is a requirement that there be a predetermined number of successive high slope epochs immediately before or immediately after the ten cc of fluid have been injected. Essentially this means that in the five epoch bracket between Q−2 epochs and Q+2 epochs there must be three successive high slope epochs.

If the third phase is also completed, then extravasation is declared and the system can be set up to either automatically stop the injection or to provide a signal so that the operator or doctor can make a determination as to what to do.

The same decision making requirements apply to all flow rates from the lowest to the highest. That is, for there to be an extravasation signal, each of the following situations must occur:

(a) There must be M successive out of gate epochs detected. In the embodiment, this number M is seven at all flow rates. The seven successive out of gate epochs must occur before the system starts to look at the slope counters.

(b) There must then be N successive high slope epochs. That number is a function of injection flow rate.

(c) A certain number P of successive low slope epochs must not occur.

(d) At least Q epochs must elapse from the start of the Run State before extravasation has been declared. The number of epochs Q is the number that assures that at least a certain minimum of fluid has been injected into the patient. In the embodiment involved, that minimum is ten cc of fluid. This means that Q is equal to fifty epochs at one cc per second and only ten epochs at five cc per second.

(e) At epoch Q, there must be R successive high slope epochs. In the embodiment disclosed, R is equal to three at all flow rates.

With the above description of the Run State in mind, FIG. **4** provides a useful logic chart or flow chart description of the main features of the Run State. As shown therein, the first step **70** is to determine that there are M successive out of gate epochs. If there are, then at step **72**, N successive high slope epochs have to be detected. If they are, then one proceeds to the phase of accumulating Q epochs, as shown at step **76**, to come to the point where ten cc of fluid have been injected into the patient. However, if during that step **76**, a predetermined number P of successive low slope epochs occur as indicated at step **74**, the process is set back to step **72**.

As indicated earlier, the value of N is an inverse function of flow rate.

Once Q epochs have passed, extravasation will be declared as indicated at step **80** if R successive high slope epochs are indicated by the End Slope Epoch Counter in the five epochs that bracket the epoch Q. If those three successive high slope epochs are not found, the process resets to the step **72**.

FIG. **5** provides a more detailed flow chart of the phases of the Run State wherein the epoch slopes are calculated and employed for the determination of extravasation.

As shown therein, the initial step **82** involves the requirement that there be the M consecutive epochs out of the gate in order to initiate the slope calculations. M equals seven in this embodiment. When there are seven consecutive out of gate epochs, then as indicated at step **84**, all three slope counters are set to zero.

The system then proceeds to calculate each epoch slope as indicated at step **86**. A determination is made (step **88**) as to whether or not each epoch slope is high or low. If it is low (that is, not high) then at step **90** the High Slope Counter is set to zero. If the epoch slope is high, then step **92** increments the Slope Counter. Step **94** then determines if the High Slope Counter equals N; which in this embodiment is four or seven depending on flow rate. The next step, step **96**, is to continue to calculate each epoch slope and determine whether at step **98** the slope is high or low. It should be noted that because of the step **90**, for the High Slope Counter to equal N at step **94**, there must be N consecutive high slopes. When step **98** identifies a high slope, the High Slope Counter and End Slope Counter are both incremented and the Low Slope Counter is set to zero (step **100**). However if step **98** identifies a low slope, the High Slope Counter and the Low Slope Counter are both incremented and the End Slope Counter is set to zero (step **102**).

The next step **104** is to determine if the Low Slope counter has a count equal to or greater than P; which in this embodiment has a value of four. Because at step **100** the Low Slope Counter resets in response to a high slope at step **98**, the Low Slope Counter will equal P only if there are P successive low slopes. If there are P successive low slopes at step **104** then, as indicated, all three slope counters are set to zero and the slope calculations are started from the beginning.

However, if the Low Slope Counter never equals P, step **106** determines if the High Slope Counter is equal to Q. Q is the number of epochs to establish that the predetermined minimum injection fluid of ten cc has been completed. The value of Q reflects the fact that there is fluid injection during the M epochs at step **82**.

When the High Slope Counter equals Q, then step **108** determines whether or not the End Slope Counter has a count of R, which in this embodiment, is three.

As described earlier, in one embodiment there is an additional routine wherein if the End Slope Counter does not read "3", then two additional epochs are processed to see if the reading of "3" is obtained, before the decision to reset or declare extravasation is made.

Certain Variations.

Although this invention has been described in connection with a particular embodiment, it would be obvious to one skilled in the art that various modifications can be made and would be made in connection with adapting to particular environments or if a different trade-off of false-positives and false-negatives were desired.

For example, there are a number of numerical parameters which could be adjusted to provide what a user might consider a more desirable or optimum arrangement. Such items as the size of the sliding window, the number of ccs in each injection before extravasation can be signaled and the band defined by the gate could be adjusted to provide different trade-offs of low false-positive and greater specificity. The inventive concepts are best defined in the claims and not in the particular value of the decision making parameters.

With reference to FIG. **4**, the number of successive high slopes required at stage **72** might be increased beyond seven for low flow rates such as the flow rates between 0.25 and 1.5. As another example, the number of successive low slopes required for reset of the slope calculation at stage **74** might well be increased to a number greater than four at very low flow rates. Furthermore, it should be recognized that the criteria that P equals four at step **74** means that in effect this step has no meaningful impact at the higher flow rates and in particular flow rates greater than 3.1 cc per second.

One area that might be considered for variation in the above disclosure is that at very low flow rates (those well under one cc per second) the size of the slope sliding window which is used to make a slope calculation might be increased to greater than seven. This is a detail and adaptation that one skilled in the art would make depending upon the refinements desired and the trade-offs looked for.

Although the filter and gate envelopes are set in the Run State at values based on the baseline going into the Run State, in one embodiment an adjustment is made in the filter and gate envelopes at the end of 45 seconds to reflect whatever change there may have been in the epoch impedance average at that point.

What is claimed is:

1. The method of detecting extravasation that may occur when a needle is inserted into a patient for the purpose of delivering fluid into the patient's vascular system comprising the steps of:

prior to the delivery of fluid, establishing an impedance baseline for patient tissue impedance near the tip of the needle;

determining an impedance slope value based on deviations from said baseline for each of a plurality of time based epochs during the delivery of fluid, and

signaling extravasation when said slope values are outside a first predetermined threshold with a consistency that meets a predetermined consistency criterion.

2. The method of claim **1** wherein:

said predetermined consistency criterion includes the combination of (a) a first predetermined number of out of threshold slopes, and (b) a second predetermined number of consecutive out of threshold slopes subsequent to the infusion of a predetermined volume of said fluid.

3. The method of claim **2** wherein said first predetermined number is of consecutive out of threshold slopes.

4. The method of claim **2** wherein said first predetermined number is inversely proportional to the rate at which fluid is delivered.

5. The method of claim **2** wherein said first predetermined number is greater than said second predetermined number.

6. The method of claim **2** wherein said step of determining a slope value comprises determining a best fit slope value over a predetermined number of epochs adjacent to the epoch for which said slope value is determined.

7. The method of claim **2** wherein said second predetermined number of out of threshold slopes commences after said first predetermined number of out of threshold slopes is determined.

8. The method of claim **2** wherein:

a sliding window of a plurality of epochs is employed to provide a base for the slope value determination, each slope value determination being based on a set of epochs that include epochs on which the preceding slope value determination was made.

9. The method of claim **1** wherein said step of determining a slope value comprises determining a best fit slope value over a predetermined number of epochs adjacent to the epoch for which said slope value is determined.

10. The method of claim 1 wherein:

a sliding window of a plurality of epochs is employed to provide a base for the slope value determination, each slope value determination being based on a set of epochs that include epochs on which the preceding slope value determination was made.

11. The method of claim 1 further comprising the steps of:

establishing said impedance baseline based on a first sliding window of epochs to provide an epoch impedance baseline,

establishing a noise exclusion gate around said epoch impedance baseline, and

during the delivery of fluid, providing a count of the number of consecutive epoch impedance averages which lie outside said gate,

said step of signaling extravasation further requiring that said count of consecutive epoch impedance averages outside said gate exceeds a first value.

12. The method of claim 11 further comprising the steps of:

prior to said step of establishing an epoch impedance baseline, determining that there are a predetermined number of successive epochs each of which have an impedance average within a predetermined window.

13. The method of detecting extravasation that may occur when a needle is inserted into a patient for the purpose of introducing fluid into the patient's vascular system comprising the steps of:

prior to the delivery of fluid, establishing an epoch impedance baseline for patient tissue impedance near the tip of the needle based on a first sliding window of epochs,

establishing a noise exclusion gate around said epoch impedance baseline,

during the delivery of fluid, counting the number of consecutive impedance averages outside of said gate to provide a first count,

establishing a second sliding window of epochs,

determining an impedance slope for epoch impedance values over each of said second sliding windows of epochs,

counting the number of consecutive ones of said impedance slopes having a value outside of a predetermined range to provide a second count,

counting the total number of said impedance slopes having a value outside of said predetermined range to provide a third count,

signaling extravasation when (a) said first count is greater than a first predetermined number, (b) said second count is greater than a second predetermined number, and (c) said third count is greater than a third predetermined number.

14. The method of claim 13 further comprising the steps of:

counting the number of consecutive ones of said impedance slopes adjacent to said third predetermined count having a value outside of said predetermined range to provide a fourth count, and

wherein said step of signaling extravasation further requires that said fourth count be greater than a fourth predetermined number.

15. The method of claim 14 further comprising the steps of:

counting the number of consecutive ones of said impedance slopes having a value inside of said predetermined range, and

resetting to said steps of counting to provide said first count.

16. The method of claim 14 wherein said first predetermined number is a count of consecutive averages outside said noise exclusion gate and wherein said first count is reset to zero when an epoch average falls within said noise exclusion gate.

17. The method of claim 13 further comprising the steps of:

counting the number of consecutive ones of said impedance slopes having a value inside of said predetermined range, and

resetting to said steps of counting to provide said first count.

18. The method of claim 17 wherein said first predetermined number is a count of consecutive averages outside said noise exclusion gate and wherein said first count is reset to zero when an epoch average falls within said noise exclusion gate.

19. The method of claim 13 wherein said second and third predetermined numbers are inversely proportional to the rate at which fluid is delivered.

20. The method of claim 19 wherein said third predetermined number is greater than said second predetermined number.

21. The method of claim 13 wherein said second sliding windows include epochs that contribute to said first count.

22. The method of claim 13 wherein said first predetermined number is a count of consecutive averages outside said noise exclusion gate and wherein said first count is reset to zero when an epoch average falls within said noise exclusion gate.

* * * * *

Aug. 23, 1938. H. W. SEIGER 2,127,538

SIGNALING DEVICE

Filed Sept. 26, 1936

Fig. 1.

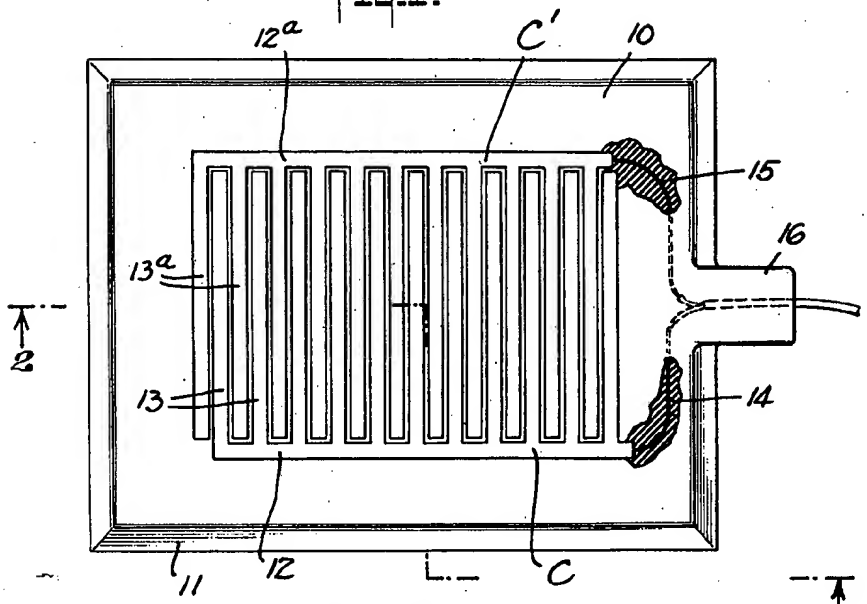


Fig. 2.

Fig. 3.

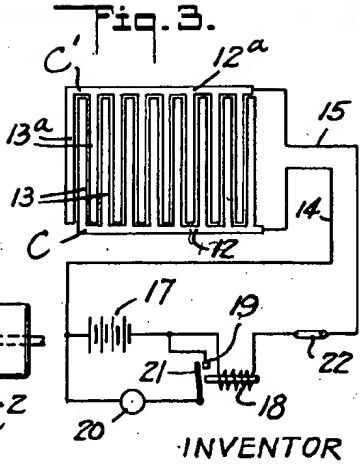
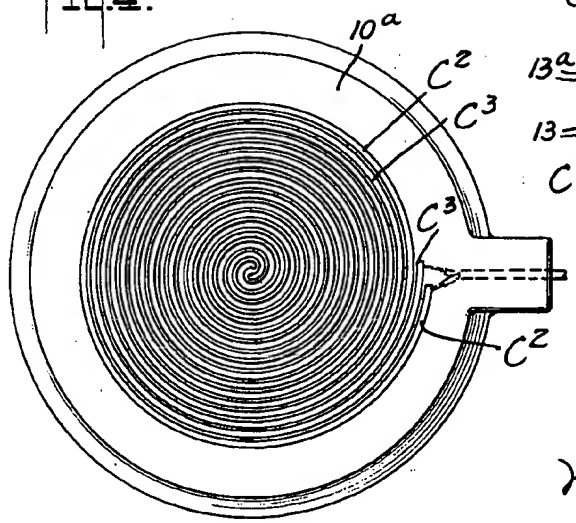


Fig. 4.



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08/12/2003, EAST Version: 1.04.0000

Pat nted Aug. 23, 1938 2,127,538

UNITED STATES PATENT OFFICE

2,127,538

SIGNALING DEVICE

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Application September 26, 1936, Serial No. 102,726

4 Claims. (Cl. 128—138)

This invention relates generally to alarm systems, and more particularly to an electrical device for use in signaling the wetting of a bed or bed clothes by the occupant thereof.

An object of the invention is to provide a device which, in its association with an infant in its crib, activates a suitable visual or audible signal when the infant urinates, so as to enable the infant's diaper to be changed immediately in order to avoid prolonged exposure of the infant to a cold wet diaper, with the attendant danger of contracting bronchopneumonia, which is the chief cause of high mortality in infants under eight months of age. The reduction in diaper rashes and irritations, due to prolonged contact of the infant's delicate skin with its urine, is another direct benefit resulting from use of the device.

Another object of the invention is to provide a wet diaper signaling device which is structurally characterized to enable its use without discomfort to the infant and in entire safety from electrical shock or injury, while insuring that the signal will be activated upon the closing of a circuit by the electrolytic action of salts in the infant's urine forming a current conducting bridge between normally insulated conductors embedded in the device.

A further object of the invention is to provide a signaling device characterized by its structural simplicity and sanitary features, requiring no replacement of any circuit controlling element or substance rendered inactive and unfit for further use by urine, as embodied in devices heretofore proposed.

With these and other objects in view, the invention consists in the following combinations and arrangements of elements as set forth in the following specification and particularly pointed out in the appended claims.

In the accompanying drawing,

Figure 1 is a plan view of the invention;

Figure 2 is a longitudinal sectional view taken on the line 2—2 of Figure 1;

Figure 3 is a diagrammatic view illustrating a preferred form of electrical circuit embodied in the invention;

Figure 4 is a plan view of a modified form of the invention.

Referring specifically to the drawing and particularly to Figures 1 to 3, inclusive, the invention comprises a relatively thin and flexible pad 10 of soft material such as elastic rubber having high electrical insulating properties. The pad is rectangular in outline and its marginal edge is beveled as indicated at 11 so as to avoid any shoulder or corner which might cause discomfort to an infant when the pad is disposed beneath the diapered portion of the infant lying in its crib.

Embedded in one side of the pad and bonded thereto so as to be exposed and flush with the top surface of the pad, are contact elements C and C' constructed from thin and flexible sheet metal to provide rectilinear bars 12 and 12a from which project at a right angle and in opposite directions fingers 13 and 13a. The fingers of the respective bars are alternately arranged in parallelism so as to interfit in sufficiently spaced relationship to be normally insulated electrically from each other by the pad, all as clearly shown in Figure 1.

Conductor wires 14 and 15 are embedded in the pad and are connected to the respective bars 12 and 12a. These wires extend through a flat handle 16 formed integrally with the pad at one end thereof, and are included in a relay circuit with a local battery 17 of 4½ or 6 volts, and the winding of a relay 18.

The fixed contact 19 of the relay forms part of an alarm circuit including the battery 17, a signal 20 which may be audible or visual and the relay armature 21 which is associated with the relay winding to close the alarm circuit when the winding is energized by closing of the relay circuit, all as clearly shown in Figure 3. A main switch 22 is included in the relay circuit to control the latter.

The operation of the invention is as follows:

With the signal 20 located at a suitable place to be seen or heard by one in attendance to an infant, and with the pad 10 disposed beneath the diapered portion of the infant when lying in its crib, it will be clear that when the infant urinates, the wet diaper will form a current conducting bridge across one or more of the fingers 13 and 13a to electrically connect the contact elements C and C', thus closing the relay circuit, it being assumed, of course, that the main switch 22 is closed.

As the relay 18 is now energized, the alarm circuit will be closed through the relay switch formed by the contact 19 and armature 21, so as to activate the signal 20 and thus indicate that the infant's diaper should be changed. The main switch 22 can be opened should circumstances prevent the immediate changing of the diaper, so as to prevent continued activation of the signal. It will be appreciated that the alarm circuit can be provided with a domestic source of current supply and a suitable step-down trans-

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former (not shown) in order to avoid a large drain of current upon the local battery 17.

Should the diaper be changed immediately, it is, of course, not necessary to open the main switch 22, as the relay circuit will be broken upon removal of the wet diaper from the pad. The device requires no adjustment or handling to render it ready for re-use, and it is not necessary that the pad be dried or wiped off after each operation. The pad can be washed occasionally to maintain it in a proper sanitary condition, but other than this operation, the device requires no servicing. The flow of current in the relay circuit by the closing thereof as a result of the electrolytic action of salts in the infant's urine is so small as to be incapable of causing any sensation to the infant even though its bare buttocks were to rest directly on the contact elements. Thus no harm to the infant would result from the use of the device, and the flexible pad would cause no discomfort.

The form of device shown in Figure 4 operates upon the same principle as the form just described and differs structurally therefrom by the provision of a circular or ovate pad 10a in the top surface of which are embedded so as to be exposed and flush therewith, contact elements C2 and C3. The elements are in the form of flexible wires spirally arranged alternately in sufficiently spaced relation for their adjacent convolutions to be normally insulated electrically from each other by the pad. As the operation of this form of the invention is identical to that of the form previously described, further description is deemed unnecessary.

It will be appreciated that it is not necessary to use a wet diaper to create an electrical bridge between the contact elements on the pad 10, but that any absorbent material wet with urine or even a sufficiently thick film of urine alone will act as the electrical bridge across the contact elements. Thus with a pad of a larger size, the device can be used as a signal by adults with mental disorders, motor and sensory paralysis around the bladder area, or any form of involuntary emptying of the bladder.

What is claimed is:

1. In a signaling device of the class described, a thin pad of soft rubber which is non-absorbent to aqueous solutions and which is adapted to be disposed beneath the diapered portion of an infant in its crib; and contact elements embedded in the pad to be exposed from and flush with a surface of the pad in sufficiently spaced relationship to be normally insulated electrically from each other by the pad, yet be electrically bridged by urine wetting the infant's diaper.

2. In a signaling device of the class described, a pad of insulating material which is non-absorbent to aqueous solutions; and flexible contact elements embedded in the pad and composed of a multiplicity of portions distributed over the area of the pad embedded therein and exposed from one surface thereof in sufficiently spaced relationship to be normally insulated electrically from each other by the pad but which are adapted to be bridged by an electrolyte.

3. In a signaling device of the class described, a pad composed of an integral body of flexible and electrically insulating material which is non-absorbent to aqueous solutions, and flexible contact elements of current conducting material having portions embedded in and exposed from one surface of the pad and spaced apart so as to be electrically insulated from each other but which will be bridged by an electrolyte.

4. In a signaling device of the class described, a pad of insulating material which is non-absorbent to aqueous solutions, contact elements embedded in the pad and exposed from one face thereof and substantially flush with a surface of the pad, said contact elements being spaced sufficiently from each other to be normally insulated electrically from each other by the material in the pad, said contacts adapted to be bridged by an electrolyte.

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08/12/2003, EAST Version: 1.04.0000

United States Patent [19]

Ward et al.

[11] **Patent Number: 4,941,882**

[45] **Date f Patent: Jul. 17, 1990**

[54] **ADHESIVE DRESSING FOR RETAINING A CANNULA ON THE SKIN**

[75] Inventors: **William J. Ward; Joanne Shorthouse,** both of Hull, United Kingdom

[73] Assignee: **Smith and Nephew Associated Companies, p.l.c.,** United Kingdom

[21] Appl. No.: **165,627**

[22] Filed: **Mar. 8, 1988**

[30] **Foreign Application Priority Data**

Mar. 14, 1987 [GB] United Kingdom 8706116

[51] **Int. Cl.**[5] **A61M 5/32**

[52] **U.S. Cl.** **604/180;** 128/DIG. 26; 604/305

[58] **Field of Search** ..... 128/155, DIG. 26, 207.17, 128/335; 604/180, 239, 240, 289, 305

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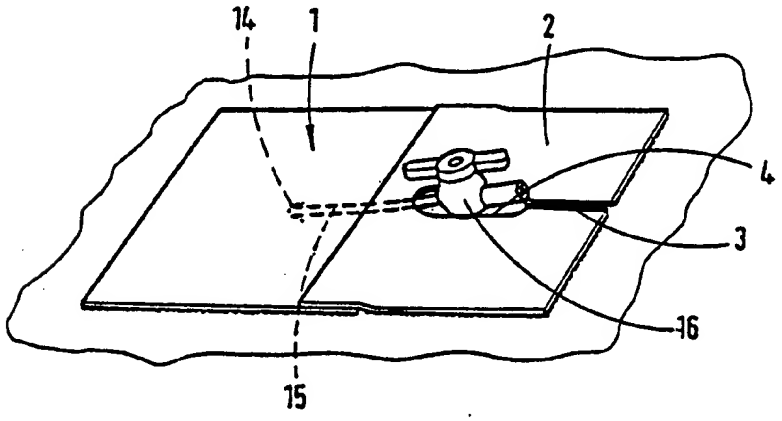
Primary Examiner—Randall L. Green
Assistant Examiner—Paul Prebilic
Attorney, Agent, or Firm—Jacobs & Jacobs

[57] **ABSTRACT**

A dressing for retaining a cannula on the skin is described. The dressing comprises a backing film coated on one face with an adhesive layer and with first and second release sheets covering the adhesive layer. A hole and a dividing line are cut through the dressing and second release sheet so that the dividing line extends from the hole to one edge of the dressing and the edge of the second release sheet. In use when the second release sheet is removed the hole in the dressing fits around the indwelling cannula. In a preferred form a portion of the dressing comprises an adhesive coated handle which is stiffer than the remainder of the dressing and which carries the hole and dividing line.

12 Claims, 1 Drawing Sheet



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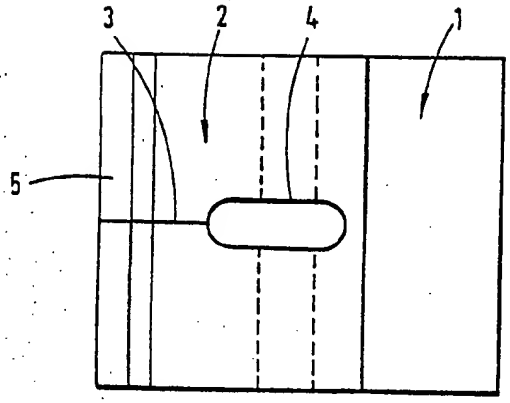

Fig. 1

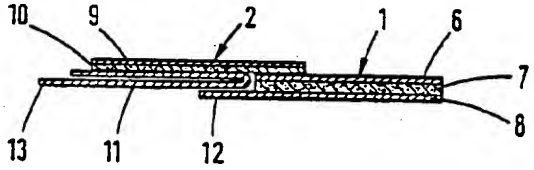

Fig. 2

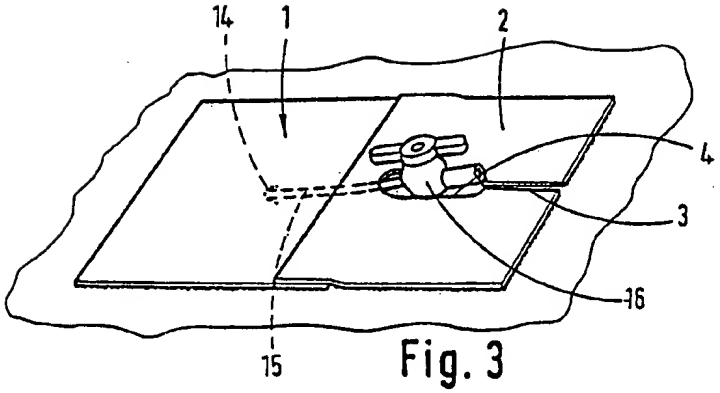

Fig. 3

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ADHESIVE DRESSING FOR RETAINING A CANNULA ON THE SKIN

The present invention relates to an adhesive dressing which is suitable for use on skin for the fixation of a catheter or a cannula and which comprises a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer and which dressing is adapted to adhere around a connection device at the proximal end of the cannula or catheter to prevent ingress of bacteria to the injection site; to methods of their preparation and use.

Adhesive dressings such as OpSite (Trademark) are frequently used to cover and secure a catheter or cannula in place at an intravenous access site. Such dressings may be referred to as i.v. dressings.

Commercially available i.v. dressings typically comprise a thin moisture vapour permeable sheet material which has on one surface a skin compatible pressure sensitive adhesive which is in turn covered by a single sheet removable protector. In use the dressing is adhered so as to cover the intravenous access site and the catheter or cannula. One problem with such dressings is that usually a bulky connector or hub is present at the proximal end of the catheter or cannula whereby connection can be made with a source of infusion fluid. This is usually in the form of a female luer lock component. Other devices may be present at this hub such as taps or injection ports or the like. The connector or hub being necessarily exposed to the atmosphere can provide a pathway whereby bacteria may reach the injection site since the connector cannot be totally enclosed beneath the dressing. One way of overcoming this problem is to use two types of dressing one covering the injection site and the second ensuring that bacteria cannot migrate from the connector along the catheter or cannula to the injection site.

A dressing has now been developed which simplifies the protection of injection sites for indwelling catheters and cannulae by providing a dressing which both covers the injection site and is adapted to retain any connector associated with the catheter or cannula in place with reduced risk of bacteria migrating to the injection site.

A second problem which is sometimes observed with such dressings is that once the protector has been removed the thin filmic adhesive dressing creases, puckers or otherwise sticks to itself and must be discarded. Many dressings have therefore included extra stiffening layers or frames or handles in an attempt to overcome this problem. However, the dressings of this invention mitigate this problem by providing the protector as a first release sheet and a second release sheet so that the first release sheet is removed to expose the adhesive on the part of the dressing which is to cover the injection site and the second release sheet is then removed to expose the remaining adhesive surface which is used to maintain the catheter or cannula in place. The second release sheet, which is folded, stabilises the dressing after removal of the first sheet and during application of the dressing.

Accordingly the present invention provides a dressing for retaining a cannula comprising a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer characterised in that there is a hole and a dividing line through the dressing and second release sheet said dividing line extending from the hole to one edge of the dressing and second release sheet whereby when the second release sheet is removed the hole in the dressing is adapted to be placed around the cannula.

By dividing line is meant a means to enable the dressing on one side of the dividing line to be separated from the dressing on the other side. A dividing line may include for example cuts and lines of perforations. Preferably the dividing line is a line of perforations.

The dividing line allows the hole and the part of the dressing around the dividing line to be placed easily around, and subsequently secure, a catheter or cannula lying on the skin.

Suitable backing films include polymeric films, papers, woven and nonwoven fabrics, but preferably the backing film comprises a flexible polymeric film. The film may comprise any of the flexible polymeric films conventionally used in i.v. dressings. The flexible film is aptly a moisture vapour permeable and bacteria proof film. In addition it is most convenient to employ a transparent material. Favoured moisture vapour permeable, liquid water impermeable, flexible films will have a moisture vapour transmission rate of at least 300 gm^{-2} 24 h^{-1} at 37° C. at a relative humidity difference of 100% to 10%, more suitably at least 400 gm^{-2} 24 h^{-1}, preferably at least 500 gm^{-2} 24 h^{-1} and most preferably at least 700 gm^{-2} 24 hr^{-1}.

Suitable flexible films for use in the invention include those described in British Patent No. 1280631 and European Patent Application Nos. 51935, 178740 and 196459. Favoured flexible polymeric films include those formed from a polyether or polyester polyurethane. Suitable polyether and polyester polyurethanes include those known as Estanes (Trademark, available from B. F. Goodrich Corp.). Preferred polyurethanes are available as Estanes 5701, 5702, 5703, 5714 and 580201. A second particularly favoured flexible film may be formed from an elastomeric polyether polyester. Preferred polyether polyesters include Hytrel 4056 (Trademark, available from E. I. du Pont de Nemours & Co.). A third particularly favoured polymeric flexible film may be formed from a polyether polyamide. Preferred polyether polyamides include Pebax 4011 (Trademark).

Suitably the thickness of the flexible films used in the invention may be from 9 to 80μm, more suitably 15 to 50μm and preferably 20 to 40μm for example 25μm, 30μm or 35μm.

A second favoured form of flexible film may be formed from any moisture vapour permeable transparent hydrophilic polymer. Suitable materials include polyurethanes, polyether polyesters, polyether polyamides, cellulosics and the like.

A favoured flexible film of hydrophilic polymer is formed from a hydrophilic polyurethane. Suitable hydrophilic polyurethanes include those having the composition and prepared by the process described in British Patent No. 2093190B. Favoured hydrophilic polyurethanes are those which contain from 5 to 50% by weight of water when hydrated, more suitably 10 to 40% by weight of water and which have a thickness when present in a dressing of from 15 to 80μm, more suitably 20 to 45μm. A preferred film of hydrophilic polyurethane has a water content when hydrated of 20 to 30% for example 25% and a thickness of 20 to 45μm, for example 30μm.

Suitably the adhesive layer on the dressing may be 15 to 65μm thick, preferably is 20 to 40μm thick, for example 25, 30 or 35μm thick. Such adhesive layers will

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generally have a weight of adhesive per unit area of 10 to 75 gm^{-2}, more usually 15 to 65 gm^{-2} and preferably 26 to 40 gm^{-2}.

Suitable adhesives include those which are described in British Patent No. 1280631 and European Patent Applications Nos. 51935, 35399. Preferably, the adhesive is a polyvinyl ether adhesive such as polyvinyl ethyl ether adhesive or an acrylate adhesive such as an acrylate ester copolymer adhesive. Examples of the latter include acrylate ester copolymers which contain hydrophilic groups, for example a copolymer of 47 parts by weight butyl acrylate, 47 parts by weight 2-ethylhexyl acrylate and 6 parts by weight acrylic acid.

The adhesive may be applied to the backing film as a continuous layer or as a discontinuous layer for example as a pattern spread layer, a porous layer.

Since the dressings of the present invention are to be adhered to normal healthy skin then to avoid maceration of that skin it is arranged that the dressing will have a moisture vapour permeability of at least 300 gm^{-2} 24 h^{-1} at 37° C. and 100% to 10% relative humidity, more suitably will be at least 500 gm^{-2} 24 h^{-1} and preferably will be at least 700 gm^{-2} 24 h^{-1}.

Suitably the adhesive may contain a medicament such as an antibacterial agent. Suitably the adhesive may contain from 1 to 10% by weight of the adhesive as medicament.

Suitable antibacterial agents include chlorhexidine and salts thereof such as chlorhexidine diacetate and chlorhexidine digluconate, iodophors such as polyvinyl pyrrolidone-iodine, silver salts such as silver sulphadiazine and polymeric biguanides for example those antibacterial agents known as Vantocil (Trademark) which is polyhexamethylene biguanide hydrochloride.

In a preferred dressing the adhesive contains 5% by weight of the adhesive of chlorhexidine diacetate.

In a preferred form of this dressing one portion of the dressing is a handle. The handle will have an adhesive layer on one surface so that it may be adhered to the skin of the patient when the dressing is in place. Normally prior to application of the dressing this adhesive layer will be covered by the second release sheet. In use the handle and its associated release sheet may be held in the hand whilst the first release sheet is removed from the remainder of the dressing. The adhesive coated layer is then applied over the skin puncture site. The second release sheet may then be removed and the handle adhered to the skin. The handle is made from a different material to the rest of the dressing and since it is not meant to cover the skin puncture site need not be bacterial-proof through this property is desirable. It is clear therefore that in a preferred form the backing layer of the dressing comprises a handle and a flexible sheet which forms the rest of the dressing. The flexible sheet is aptly formed from any of the materials which are suitable for the backing layer as described hereinbefore especially a moisture vapour permeable, liquid water impermeable, flexible polymeric film. The handle may be attached to the rest of the dressing by any conventional means such as adhesives or by bonding the handle and flexible sheet together by means of heat. In this preferred form of the dressing the hole and dividing line are located in the handle of the dressing.

From the foregoing it is clear that the adhesive surface on the handle and the adhesive surface on the flexible sheet will be on the same side so that both may be adhered to the body.

The handle used in the dressing of the invention can suitably be a film, sheet or web. Suitable handles can be made of a wide variety f materials including paper, non-woven fabric, woven fabric and films, sheets or webs of polymers including polypropylene, polyethylene, copolymers thereof and blends thereof and blends including polystyrene, polyester and polyvinyl chloride.

Particularly apt materials for forming the handle include paper, porous polyvinyl chloride sheet such as that sometimes known as Porvic (Trademark) which is conventionally used in the manufacture of first aid dressings, non-woven fabric such as spun-bonded polyester fabric (Sontara, Trademark), polyester film (Melinex, Trademark), woven acrylic fabric, embossed films of low or high density polyethylene or polypropylene, integral nets formed by the fibrillation of embossed films and oriented polypropylene films.

However, particularly preferred materials for forming the handle are integral nets particularly those formed by the fibrillation of thermoplastic embossed polyolefin films comprising low and high density polyethylene, polypropylene or copolymers or blends thereof or blends of polyolefin with polystyrene. Such nets are described in British Patents Nos. 1495151 and 1531715.

The handle has a dividing line extending inwardly from the edge of the handle in a direction towards the flexible sheet portion of the backing film of the dressing. The dividing line leads to the hole cut within the area of the handle. The hole preferably extends into the overlap area where the handle and flexible sheet overlap.

The hole may be of any shape such as square, rectangular, circular, oval and the like. It is preferred that the hole is oval in shape as this shape accommodates the shape of the connector and thereby forms a better seal between the dressing and the connector. Suitably the long axis of the hole may be from 20 to 30 mm in length and preferably 23 to 27 mm in length for example 25 mm and the short axis of the hole may be from 5 to 15 mm, and preferably 7 to 11 mm for example 9 mm.

The second release sheet which may cover the exposed adhesive of the handle when present may be in a folded form and may be cut along with the handle so that the release sheet has a slit and opening or alternatively the release sheet may be merely perforated.

The handle may be colour coded, for example the handle may be green or yellow or pink.

Since the handle is to be adhered to the skin it is preferred that the handle when coated with adhesive should have a moisture vapour transmission rate of at least 300 gm^{-2} 24 h^{-1} at 37° C. and 100% to 10% relative humidity when measured by the Payne Cup Method. More suitably the adhesive coated handles should have a rate of at least 500 gm^{-2} 24 h^{-1} and preferably should be at least 700 gm^{-2} 24 h^{-1}. The handle may then be safely adhered to the skin without the risk of causing maceration to the underlying normal healthy skin.

An adhesive such as one of those described in British Patent No. 1280631 or European Patent Application No. 35399 may be spread onto the smooth surface of the net as hereinbefore described, that is the one which was embossed with the series of grooves. A particularly suitable adhesive is an acrylate ester copolymer adhesive formed from the polymerisation of 47 parts 2-ethylhexyl acrylate, 47 parts butyl acrylate and 6 parts acrylic acid. This combination of net and adhesive gives

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a tape of both high moisture vapour permeability which is particularly apt for the dressings of the present invention. If the adhesive layer is continuous the moisture vapour transmission rate is approximately 800 gm^{-2} 24 h^{-1} and if the adhesive layer is porous the rate may be as high as 8000 gm^{-2} 24 h^{-1}, when measured at 37° C. and 100% to 10% relative humidity.

Suitably the handle may be 1.0 cm to 6.0 cm in width and preferably 2.0 to 5.0 cm in width, for example 2.8 cm, 3.0 cm or 3.8 cm in width. The width of the margin of the handle which is adhered to the edge margin of the flexible sheet is then suitably 0.1 to 1.0 cm, more suitably is 0.15 to 0.5 cm and is preferably 0.2 to 0.3 cm.

In order to avoid maceration of the underlying skin in this overlap area of the flexible sheet and handle the dressing in this area will favourably have a moisture vapour transmission rate of at least 300 g^{-2} 24 h^{-1} at 37° C. and 100% to 10% relative humidity difference, more favourably the rate will be at least 500 gm^{-2} 24 h^{-1} and preferably be at least 700 $gm^{31\,2}$ 24 h^{-1}.

In a further embodiment of this invention a further handle may be placed on the edge of the dressing opposite the handle with the dividing line and hole.

Suitable release sheets for covering exposed adhesive areas prior to use include silicone release coated papers and plastics coated papers and release coated films such as silicone coated polyethylene. A favoured release sheet is a silicone release/polyethylene coated paper known as Steralease No. 15 (Trademark, available from Sterling Coated Paper Limited).

The adhesive layer of the dressing is protected by a first and second release sheet.

In a preferred form the second release sheet protects the adhesive layer on the handle and is folded back to form a second tab. The first release protects the adhesive layer on the flexible sheet of the dressing and a part of this first release sheet, which is not in contact with the adhesive layer, forms a first tab which covers part of the second tab. Preferably the second tab is longer than the first tab. In a further preferred embodiment the second tab when folded back extends beyond the edge of the dressing.

Preferably the second release sheet which protects the adhesive layer on the handle has a hole and a dividing line in it matching exactly the hole and dividing line in the handle.

In a further preferred form of the dressing a portion is cut out of the second tab so that when it is folded back on the second release sheet the cut-out portion of the second tab will overlay that portion of the hole in the second release sheet covered by the second tab. Preferably the first tab has an aperture cut so that when it covers the second tab the edges of the aperture line up with the edges of the hole in the second release sheet and the handle.

The dressing of the invention will usually have a rectangular shape. Suitable dressings have a size of 5 cm × 5 cm to 20 cm × 20 cm for example 6 cm × 8 cm, 10 cm × 10 cm, 10 cm × 15 cm, 15 cm × 15 cm etc.

The dressing of the invention is preferably sterile. The dressing of the invention is advantageously provided within a bacteria proof pack such as a sealed aluminium foil or paper/plastics film pouch. Sterilization of the dressing can be carried out by a conventional sterilizing method such as ethylene oxide, electron or gamma radiation.

In another aspect the invention provides a process of making a dressing of the invention which comprises attaching the edge margin of a handle to an edge margin of a flexible sheet and then the handle has a dividing line cut inwardly from one side edge and a hole punched in the handle area.

Suitable backing films, flexible sheets and handles for use in the process of the invention are described hereinbefore in relation to the dressing of the invention.

The backing film may be formed by casting or extrusion onto a support film, usually the non-release surface of a conventional release paper or polymer. The adhesive layer may be formed by casting or transfer coating onto the surface of the flexible film. The adhesive surface of the flexible film may then be transferred onto the release surface of the second release sheet and then the first release sheet placed over the remaining adhesive surface so that the tab portion overlaps onto the second release sheet. The three layer laminate is then cut into a strip having the width of the required dressing. The dividing line and hole are then cut in the dressing.

The handle when present may be formed by transfer coating an adhesive layer on a release paper onto the material forming the handle. This may then be cut into a strip of the appropriate width and attached to the edge of the flexible sheet portion of the backing film. The second release sheet is applied to the adhesive surface of the handle and the first release sheet is applied to the adhesive surface of the flexible sheet. The dividing line and hole are then cut in the handle area and second release sheet.

In another aspect the present invention provides a method for retaining a cannula on the body employing a dressing comprising a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer in which there is a hole and a dividing line through the dressing said dividing line extending from the hole to one edge of the dressing and second release sheet which method comprises separating the dressing along the dividing line and placing the part of the dressing containing the hole around the cannula, removing the first release sheet and adhering the exposed part of the dressing over the puncture site and then removing in turn the two halves of the second release sheet so that the remainder of the dressing secures the cannula on the skin.

A preferred embodiment of the present invention will now be described with reference to the accompanying drawings in which:

FIG. 1 shows a plan view of a dressing of the invention.

FIG. 2 shows a cross-section through a dressing of the invention illustrating the layers which are present therein.

FIG. 3 shows a dressing of the invention adhered to the skin and around a tap connector.

FIG. 1 shows a view from above of a dressing of the present invention. The adhesive coated flexible sheet portion of the backing film (1) is adhered to the skin over the injection site. An adhesive coated handle (2) is attached along one edge to the adhesive coated flexible sheet (1). The handle (2) has extending inwardly from one side edge a dividing line (3) and at the end of the dividing line (3) but within the boundaries of the handle (2) is a hole (4). The exposed adhesive surfaces of the flexible sheet (1) and the handle (2) are covered by first and second release sheets respectively which are removed prior to use. The second release sheet (5) which covers the adhesive on the handle (2) is in the form of a folded piece of silicone release paper which may carry

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a dividing line and hole similar to that of the handle (2) or may be perforated along the line of the dividing line (3) in the handle.

FIG. 2 shows a cross-section through a dressing of the invention showing the different layers which make up the dressing. The adhesive coated flexible sheet (1) comprises two layers, first a backing film (6) which is formed from a moisture vapour permeable polymeric film comprising for example a linear polyether or polyester polyurethane, an elastomeric polyester or other hydrophilic polymer film which has a moisture vapour transmission rate of over 1600 gm^{-2} 24 h^{-1} at 37° C. and 100% to 10% relative humidity difference. Second an adhesive layer (7) which is formed from a skin compatible adhesive such as a polyvinylethyl ether or polyacrylate ester copolymer adhesive. Suitably the adhesive is moisture vapour permeable whereby the dressing has a moisture vapour transmission rate of over 300 gm^{-2} 24 h^{-1}. Prior to use the adhesive surface is covered by a first release sheet (8) formed from a silicone coated release paper. The handle (2) is also formed from 2 layers (9,10). The first a backing layer (9) is more rigid than the backing film (1) but is also formed from a moisture vapour permeable material. Since this material is adhered to unbroken skin, the backing layer (9) may be a plasticised polyvinyl chloride film, a non-woven fabric or a net. The second layer (10) is an adhesive layer similar to that on the flexible sheet (1). The handle (2) is adhered to the adhesive coated flexible sheet (1) along one edge and the remaining exposed adhesive surface is covered by a silicone-coated second release sheet (11) suitably in the form of a folded piece. The first release sheet (8) overlaps part of the second release sheet (11) to ensure that no adhesive surfaces are left exposed. The first (12) and second (13) tabs on the first and second release sheets respectively allow the release sheets to be removed easily.

FIG. 3 shows a dressing of the invention in position at an injection site. The adhesive coated flexible sheet (1) is adhered over the injection site (14) and over the indwelling catheter (15). The hole (4) and the dividing line (3) in the handle (2) are adapted to fit round a connector (16) which in this illustration carries a tap.

In use the second tab (13) and handle (2) are held in one hand and the first tab (12) is held in the other hand. The first tab (12) is then pulled and the first release sheet (8) is removed from the adhesive coated flexible sheet (1). The adhesive coated backing film (1) is then adhered over the injection site and the catheter or cannula. The second tab (13) is then grasped and pulled and the second release sheet (11) is removed. The dividing line (3) in the dressing enables the dressing to be placed around the connector (16) so that the hole (4) in the dressing goes around the connector (16) and the two parts of the handle (2) can be adhered to the skin around the connector (14).

Alternatively the dressing may be used as follows, the perforated dividing line (3) is torn through and the two arms of the handle (2) and the hole (4) are arranged to lie on either side of the connector (16). The first tab (12) is used to remove the release sheet (8) from the adhesive surface of the flexible sheet (1) and this portion of the dressing is adhered to the skin over the injection site (14) and the indwelling catheter (15). The second tab (13) now in two parts is used to expose in turn the adhesive surfaces of the handle (2) surrounding the connector (16) which are then adhered to the skin around the connect r. Alternatively each half of the second tab in turn can be used to expose the adhesive surfaces of the divided handle such that the handle halves cross one on top of the other on the skin under the connector to form a better seal around the connector and to secure the connector more firmly.

We claim:

1. A dressing for retaining cannulae comprising a backing film coated on one surface with an adhesive layer, the backing film comprising an adhesive coated flexible sheet attached to an adhesive coated handle, the material of the handle being different from the material of the flexible sheet, first and second release sheets covering the adhesive layer in which there is a hole and a dividing line through the dressing and the second release sheet said dividing line extending from the hole to one edge of the dressing and the second release sheet, the second release sheet contacting the adhesive surface of the handle and the hole and dividing line being located within the handle, whereby when the second release sheet is removed the hole in the dressing is adapted to be placed around a cannula.

2. A dressing according to claim 1 in which the dividing line is a line of perforations.

3. A dressing according to claim 1 in which the hole is oval in which the long axis is from 20 to 30 mm and the short axis is from 5 to 15 mm.

4. A dressing according to claim 1 in which part of said second release sheet is folded back to form a second tab and a part of said first release sheet which is not in contact with the adhesive layer forming a first tab which covers part of said second tab, and wherein the second tab extends beyond the first tab.

5. A dressing according to claim 1 in which the flexible sheet is a polyurethane film of thickness from 15 to 50 μm and the handle is an integral net formed by the fibrillation of thermoplastic embossed polyolefin film.

6. A dressing according to claim 1 in which the backing film is a polyurethane film of thickness from 15 to 50 μm.

7. A dressing according to claim 1 in which the adhesive layer is formed from a acrylate ester copolymer adhesive and which has a weight per unit area of 10 to 75 gm^{-2}.

8. A dressing according to claim 1 in which the backing film coated with an adhesive layer has a moisture vapour transmission rate of at least 300 gm^{-2}24 h^{-1} at 37° C. and 100% to 10% relative humidity difference.

9. A dressing according to claim 1 in which the adhesive layer contains antibacterial agent.

10. A dressing according to claim 9 in which the adhesive layer contains 5% by weight of the adhesive layer as the antibacterial agent chlorhexidine diacetate.

11. A dressing according to claim 1 in which the dressing is sterile and is provided in a bacteria proof pack.

12. A dressing according to claim 5 in which the adhesive coated handle has a continuous adhesive layer and has a moisture vapour transmission rate of at least 800 gm^{-2}24 H^{-1} at 37° C. and 100% to 10% relative humidity difference.

* * * * *

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same concept type design.
Fig 10

widely appl.

US005469145A

United States Patent [19]

Johnson

[11] Patent Number: 5,469,145

[45] Date of Patent: Nov. 21, 1995

[54] **WET DIAPER DETECTOR**

[76] Inventor: **Lonnie Johnson**, 1640 Roswell St., Suite A, Smyrna, Ga. 30080

[21] Appl. No.: **158,612**

[22] Filed: **Nov. 29, 1993**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 890,162, May 29, 1992, Pat. No. 5,266,928.

[51] **Int. Cl.**[6] **G08B 21/00**

[52] **U.S. Cl.** **340/604**; 340/573; 128/886; 604/361

[58] **Field of Search** 340/603, 604, 340/605, 573; 200/61.05; 128/886; 604/361

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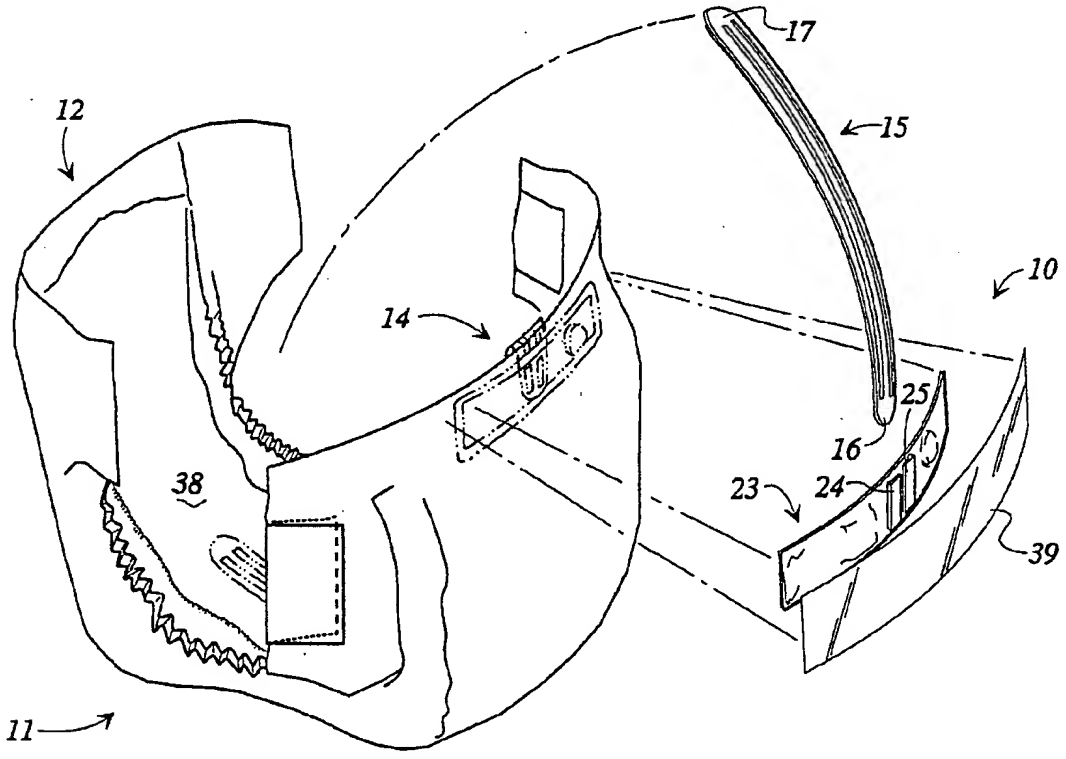
Primary Examiner—John K. Peng
Assistant Examiner—Edward Lefkowitz
Attorney, Agent, or Firm—Kennedy & Kennedy

[57] **ABSTRACT**

A wet diaper detector comprises an elongated strip of material sized to be positioned in a diaper with a portion of the strip residing in a region of the diaper subject to wetness and an end of the strip protruding from the diaper at the upper rear or front portion thereof. The strip carries a pair of spaced conductors that extend along the length of the strip and terminate at the protruding end thereof. A detector and alarm assembly is adapted to be releasably coupled to the protruding end of the elongated strip and is configured to monitor the electrical resistance between the spaced conductors of the strip. When the diaper is wet by its wearer, the resistance between the spaced conductors of the strips falls below a pre-established value whereupon the detector activates the alarm to alert an attendant to change the diaper. In one embodiment, wetness is detected capacitively. When the diaper is changed, the detector and alarm assembly is decoupled from the strip for reuse and the strip is discarded along with the soiled diaper.

13 Claims, 5 Drawing Sheets



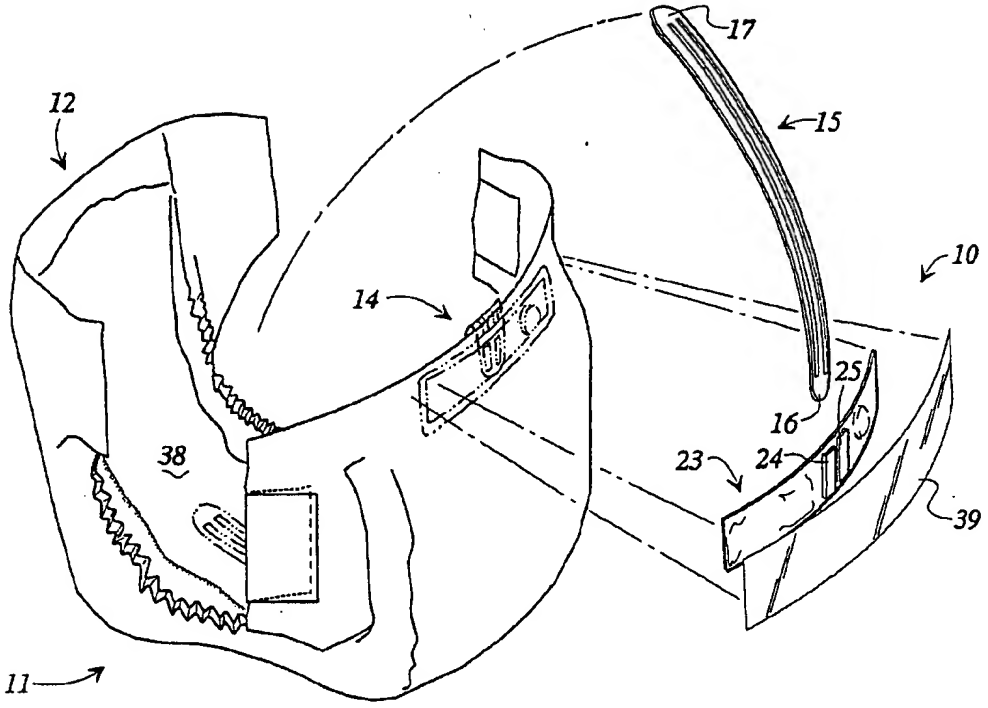


FIG 1

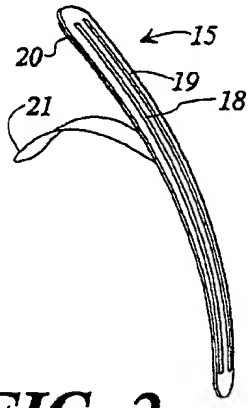


FIG 2

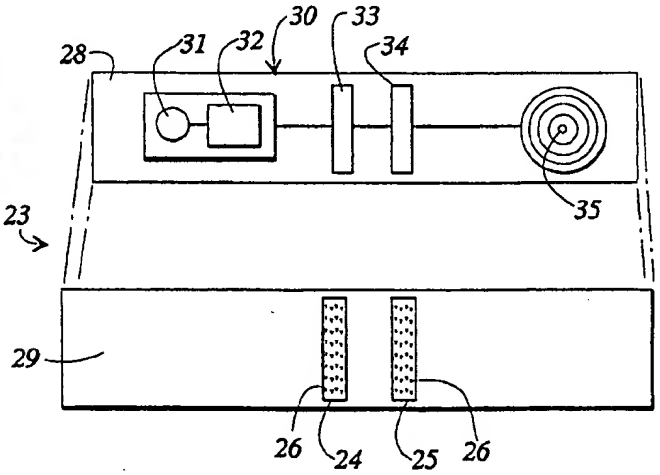


FIG 3

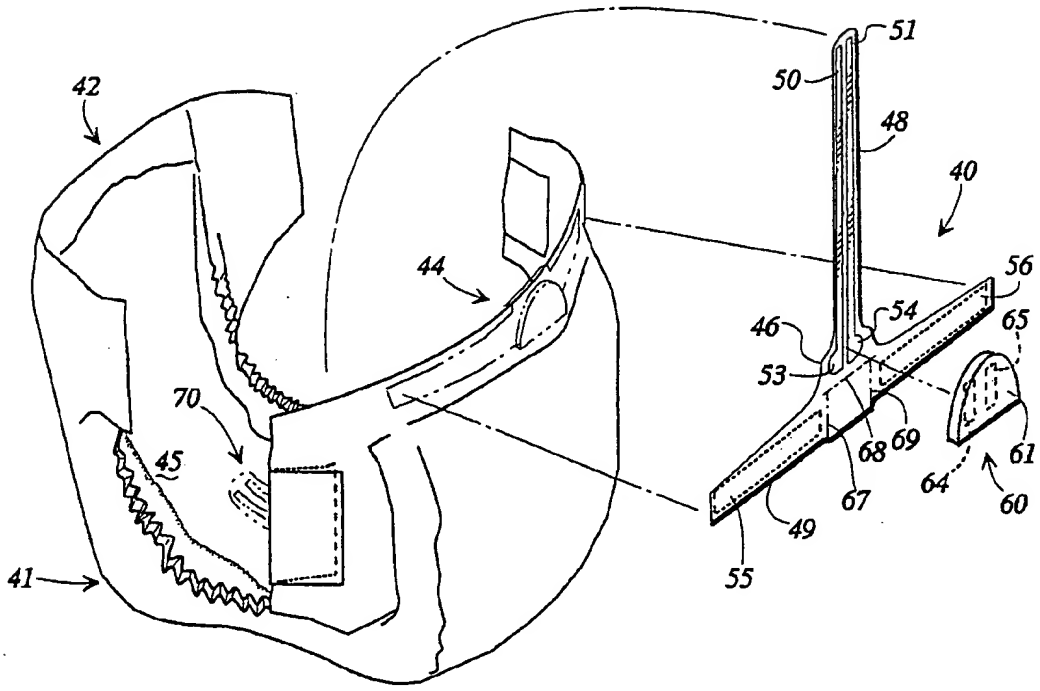


FIG 4

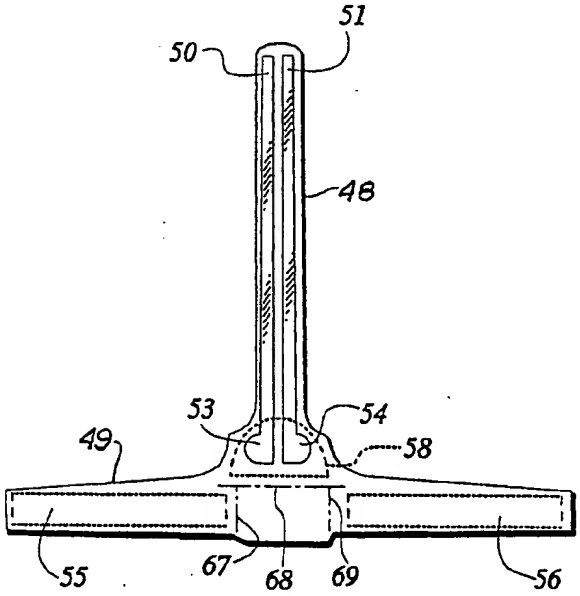


FIG 5

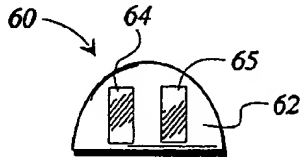


FIG 6

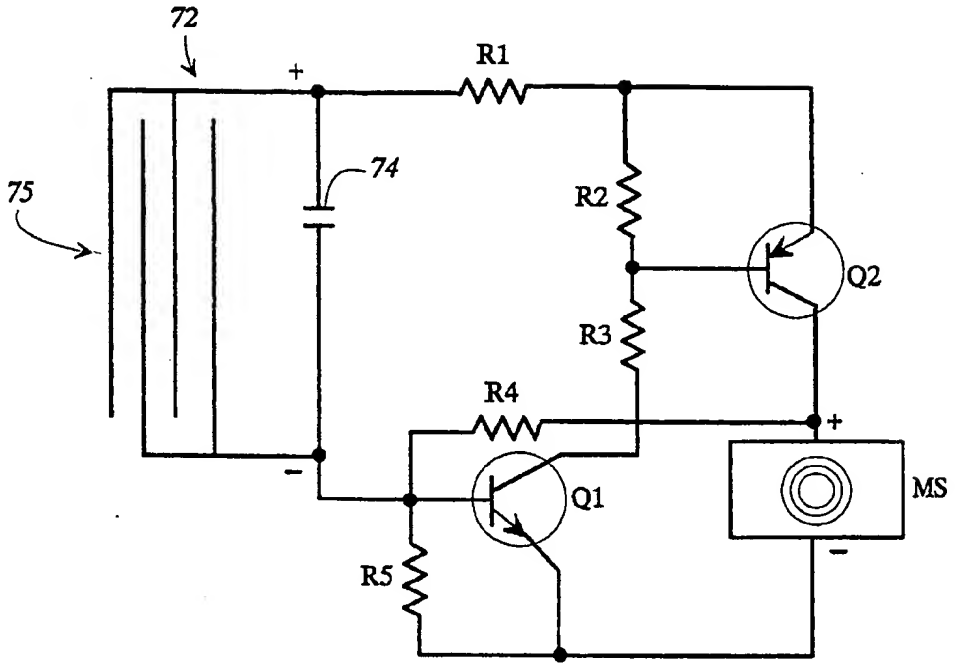


FIG 7

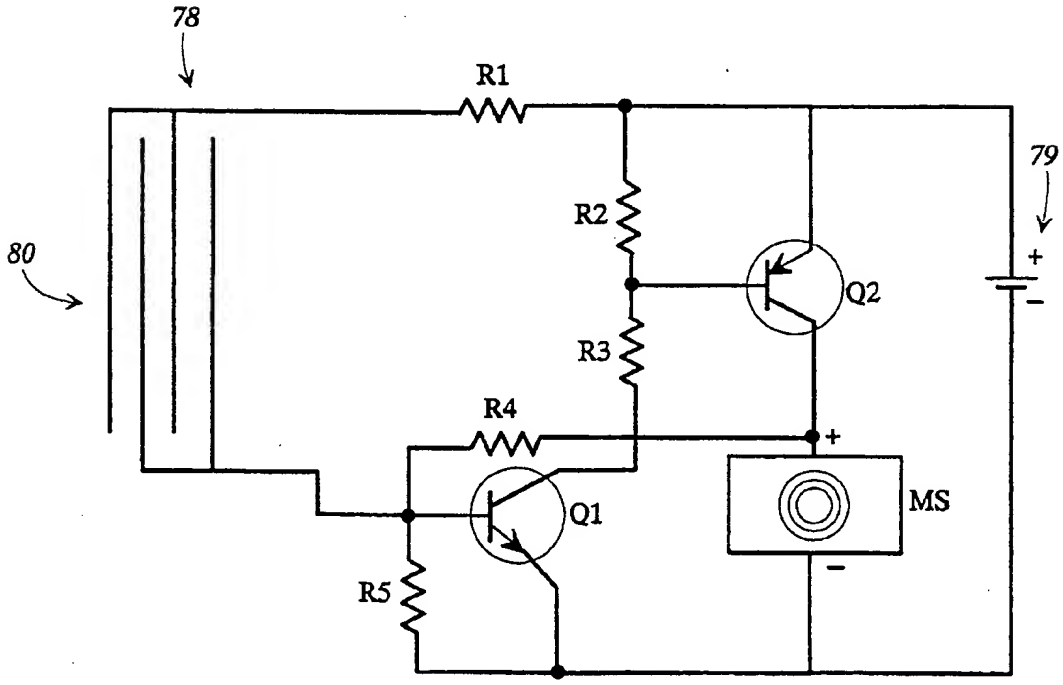


FIG 8

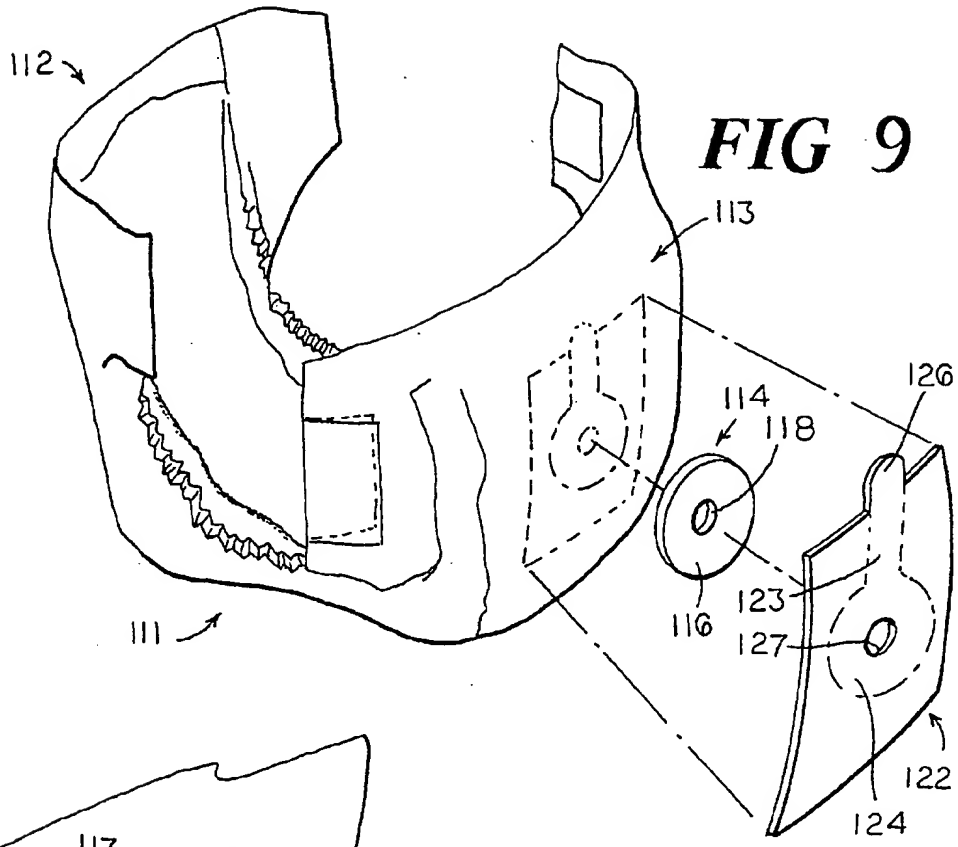

112
113
114
118
126
116
123
127
111
122
124

FIG 9

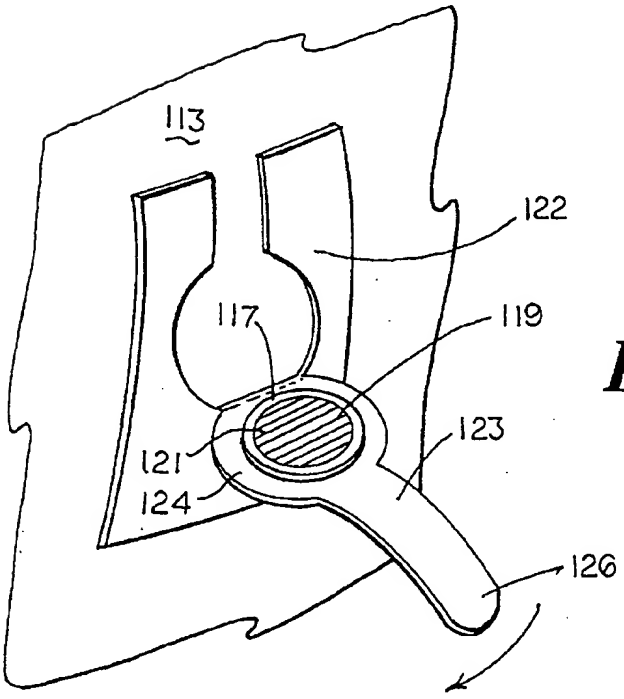

113
122
117
119
121
123
124
126

FIG 10

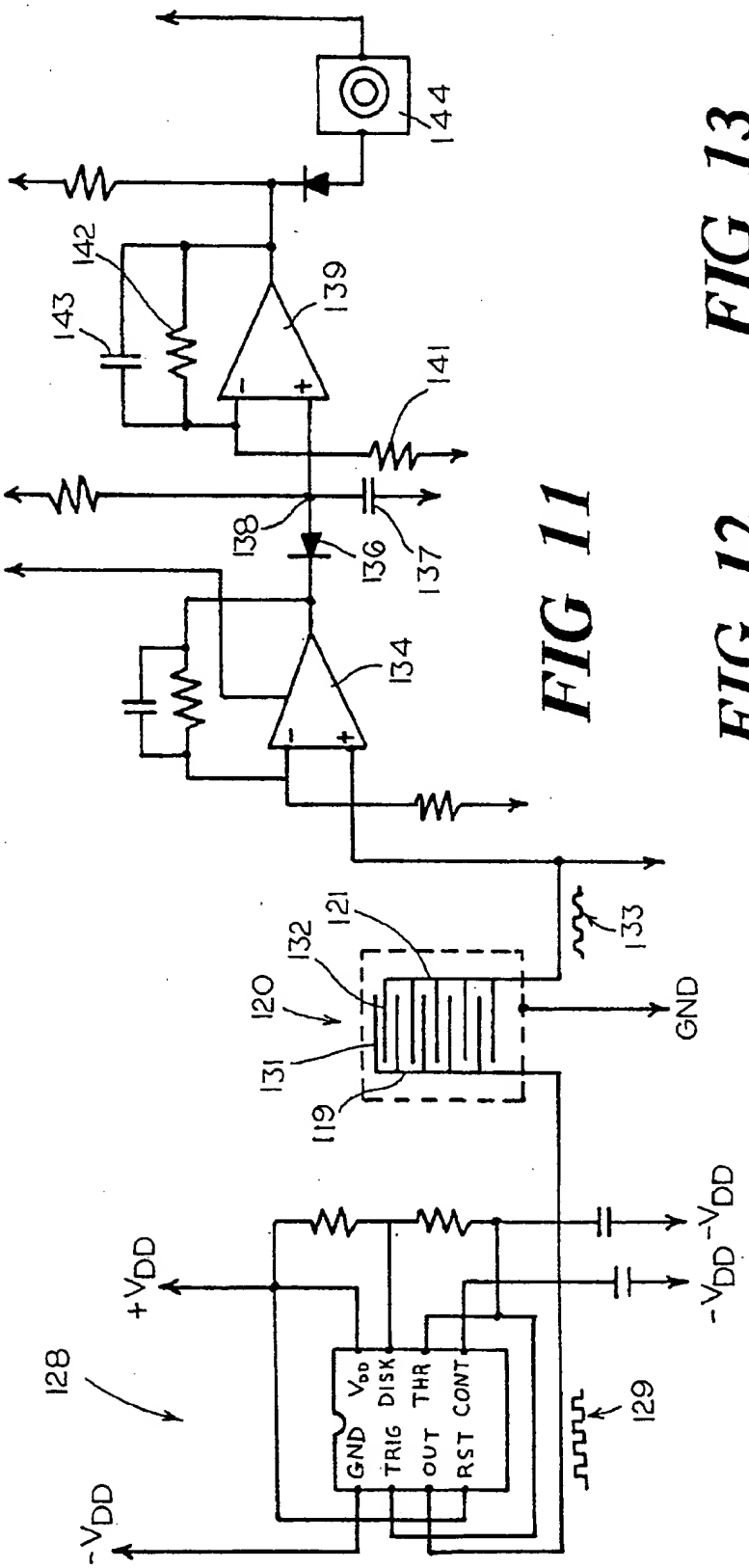


FIG 11

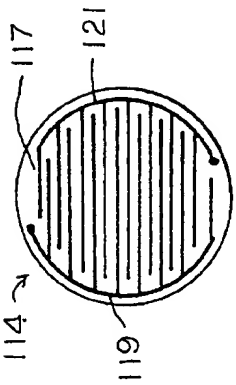


FIG 13

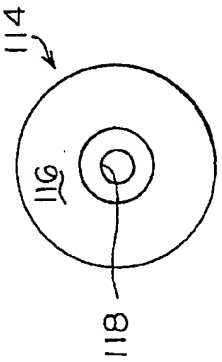


FIG 12

WET DIAPER DETECTOR

REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 07/890,162 filed May 29, 1992, now U.S. Pat. No. 5,266,928.

FIELD OF THE INVENTION

This invention relates generally to moisture sensing devices and more particularly to a wet diaper detector assembly for alerting parents or attendants to the presence of wetness in an infant's diapers or undergarments.

BACKGROUND OF THE INVENTION

Baby diaper rash is for the nursing mother one of the most enigmatic problems of infant rearing. One of the primary causes of such diaper rash is, of course, that babies frequently wet their diapers and wear the wet diapers for prolonged periods before they are changed. While a few babies tend to cry when wet, many babies do not cry, and the mothers of this latter group of babies are not alerted to the wet diaper condition until the diaper has been worn for a time sufficient to cause diaper rash.

In an effort to reduce the time during which wet diapers are in contact with a baby's skin, mothers often adhere to a specific change of diaper schedule wherein a baby's diapers are changed periodically according to a pre-established timetable. Although such diaper-changing schedules are helpful, a real reduction of time during which urine contacts the baby's skin is not often realized because no prescribed time table can anticipate an individual baby's changeable physical constitution. For example, an infant might wet its diaper immediately after a scheduled change of the diaper and thus, unknown to the mother, be left in a soiled diaper until the next scheduled change of the diaper.

Alarm devices have previously been proposed as a means for informing a parent or attendant that a wet diaper condition has occurred so that the baby's clothing can be changed and its skin cleansed to eliminate the urine/skin contact and reduce the chances of diaper rash. One example of such a proposed alarm device is disclosed in U.S. Pat. No. 3,460,123 of Bass. Bass shows a wet garment alarm system that includes a transmitter for producing a radio signal and a diaper formed with a pair of spaced conductive screens having an electrolyte disposed therebetween. The transmitter is electrically coupled to the screens and adapted to produce a radio signal when the resistance between the screens falls below a predetermined level. In use, the transmitter of Bass is secured to the upper waist portion of an infant's diaper, and the diaper is secured to its wearer with the pair of conductive screens positioned at the crotch portion of the diaper. When the diaper is wet by the wearer, urine flows into the crotch portion of the diaper and electrically bridges the space between the conductive screens thus reducing the resistance between the screens. This reduced resistance, in turn, actuates the transmitter to produce a radio signal for activating a remote alarm to alert a parent or attendant to the wet diaper condition.

Another system for detecting and signaling a wet diaper condition is disclosed in U.S. Pat. No. 4,106,001 of Mahoney, wherein a garment clip houses a moisture detector and alarm. The garment clip is adapted to be clipped onto an exposed edge of a diaper or other garment to be monitored. An elongated strip of material is detachably connected at one end to the clip and is sized to be positioned in a region of the diaper subject to wetness such as, for example, the crotch region. The strip of material includes a pair of embedded spaced electrodes that are coupled to the detector/alarm. When moisture is provided by the wearer of the undergarment, a partial short circuit occurs between the electrodes at some point along the strip of material. This short circuit is detected by the moisture detector, which activates the alarm to provide an audible indication of urination by the infant or wearer.

A similar system is disclosed in U.S. Pat. No. 4,796,014 of Chia, wherein a safety pin with spaced electrical conductors is coupled to a detector and alarm device attached to a diaper. When urine bridges the space between the electrical conductors of the safety pin, a detection circuit is completed, which, in turn, activates the alarm. The Chia device further includes a time delay circuit to ensure that the alarm does not interfere with an infant's normal urination cycle.

While these and similar devices have been somewhat successful in signaling a wet diaper condition, they still tend to exhibit numerous problems and shortcomings inherent in their respective designs. For instance, several of these devices include a pair of conductive electrodes built into the material forming the diaper itself. Such a configuration is shown in the patent of Bass. Obviously, manufacture of these types of diapers can be relatively expensive since special diaper forming machinery must be developed and implemented. Another common problem with prior art devices is that the detecting strips that reside in the diaper are configured as integral non-detachable elements of the detector and alarm circuits. With such a configuration, the entire device often must be discarded when the sensing strip becomes worn, which is inefficient and wasteful. Also, manufacturing the detection devices and alarms in some prior art devices can become complicated and costly. Finally, the mere fact that conductive electrodes must extend into the diaper to detect resistive changes when a baby wets is objectionable to many parents and, under the proper condition, could result in a mild shock to an infant wearer.

Accordingly, there exists a continuing and heretofore unaddressed need for a wet diaper detector and alarm system that is usable with a conventional disposable or non-disposable diaper, is inexpensive to produce, easy and convenient to use, does not necessarily require that conductive electrodes extend into the diaper itself, and that does not require expensive and bulky housings that must be secured to a wearer's garments. It is to the provision of such a wet diaper detector and alarm system that the present invention is primarily directed.

SUMMARY OF THE INVENTION

Briefly described, the present invention comprises a wet diaper detector and alarm system for use with conventional undergarments or diapers to alert a parent or attendant to a wet diaper condition and also to provide a dependable manner by which young children can be toilet trained. In one preferred embodiment, the wet diaper detector and alarm system of this invention comprises an elongated strip of generally absorbent material having a pair of spaced embedded conductors extending therealong. The conductor bearing strip is sized to be positioned and secured in a diaper extending through a wetness prone region thereof with one end of the strip protruding from the diaper, preferably at the front or rear waistband portion thereof. A generally rectangular flexible band supports miniaturized electronic detec-

tion and alarm circuitry and is configured to be removably attached to the protruding end of a conductor bearing strip that previously has been secured in the diaper. The band includes a pair of electrical contacts that are coupled to the detection circuit of the band with each contact being configured to become electrically coupled to a respective one of the conductors of the elongated strip when the band is removably attached to the strip end. With the band thus attached to the protruding end of a conductor bearing strip, the band and strip end can be removably mounted to the exterior of the diaper with a rectangular adhesive backed patch that covers and protects the band during use.

The electronic detector and alarm of the present invention is configured to monitor the resistance between the spaced conductors of an attached conductor bearing strip and to trigger the alarm, which preferably emits a pleasant audible melody, when such resistance falls below a pre-established threshold. When the system is properly secured to an infant's diaper as described above, the electrical resistance between the two electrical conductors of the elongated strip normally remains above the pre-established threshold when the diaper is dry. However, when the wearer wets its diaper, the resulting moisture permeates the strip therein and causes the resistance between the two conductors of the strip to fall below the pre-established threshold. As a result, the detector triggers the audible alarm to alert an adult or attendant immediately of the wet diaper condition so that the diaper can be changed.

In another embodiment of the invention, a T-shaped strip of material is adapted to be secured to a diaper with its shorter leg positioned on the outside of the diaper at the upper front or rear portion thereof and with its longer leg extending therefrom into the diaper and through the crotch area thereof. A pair of spaced conductors are disposed along the length of the longer leg and each conductor terminates in a contact at the intersection of the legs of the T-shaped strip, which normally lies on the outside of the diaper. A miniaturized detector and alarm circuit is contained within a small plastic housing having a pair of spaced external contacts positioned to engage the contacts at the strip intersection when the housing is located on the T-shaped strip at the intersection of its legs.

In use, the T-shaped strip of this second embodiment is placed in a diaper as described and the detector/alarm housing positioned at the intersection of the strip's legs with its contacts engaging the contacts of the strip. The shorter leg of the T-shaped strip, which preferably bears adhesive, is then folded up over the housing and adhesively attached to the front of the diaper to secure the detector in place. The circuitry then functions in the same way as with the previously described embodiment to signal a wet diaper condition. When a wet diaper is changed, the small detector housing is simply removed and reused while the used, inexpensive T-shaped strip is discarded with the soiled diaper.

In a third embodiment of the invention, the electronic detection and alarm circuit is housed in a small plastic button-shaped housing. The back side of the housing is provided with two conductors shaped with interleaved fingers to form a parallel plate-type capacitor that functions as a detector. The circuit includes an oscillator coupled through the capacitor detector to an amplification, rectification, and comparison circuit. In use, the button is removably fixed to the outside of a diaper adjacent a wetness prone region thereof. As long as the diaper is dry inside, the capacitive coupling between the fingers of the detector is weak and a relatively small percentage of the oscillating signal is transmitted across the capacitor. When amplified and rectified, this small signal is less than a predetermined threshold and the comparison circuit does not activate the alarm. However, when the baby wets, the urine acts as an electrolyte that significantly enhances the capacitive coupling between the finger plates of the capacitor detector. Thus, substantially more of the oscillator signal is transmitted and, when amplified and rectified, generates a signal greater than the pre-established threshold. In response, the comparison circuit activates the audible alarm signaling a wet condition. Once a diaper has been wet, the detector button is removed for reuse on a new diaper.

Thus, it is seen that an improved wet diaper detector and alarm system is now provided for detecting and signaling a wet diaper condition quickly, reliably, economically, and conveniently. The components of the system are designed so that the more expensive elements, i.e. the electronic detection and alarm circuitry, are easily removed and reused while the inexpensive conductive strip, which becomes soiled along with the diaper, is simply discarded. The system is thus highly efficient relative to prior art systems. Also, in the capacitively coupled embodiment, there are no conductive strips or any other elements that extend into the diaper itself.

The present invention provides great advantages in the care of wetting infants since it allows a wet diaper to be changed immediately, thus reducing greatly instances of urine induced diaper rash. The system is further advantageous in the toilet training of infants since its alarm can signal a parent or attendant to take the infant to a toilet immediately upon commencement of wetting. In this way, the child makes the mental connection between wetting and the toilet much quicker than with older fashioned toilet training techniques. These and other features, objects and advantages of the invention will become more apparent upon review of the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective partially exploded view of a wet diaper detector that embodies principles of the present invention in one preferred form.

FIG. **2** is a detailed perspective view of the disposable conductor bearing strip of the invention.

FIG. **3** is a partially exploded view showing a preferred construction of the rectangular component carrying band of the invention.

FIG. **4** is a perspective partially exploded view showing an alternate embodiment of the wet diaper detector of the present invention.

FIG. **5** is a top plan view of the disposable T-shaped strip of the embodiment shown in FIG. **4**.

FIG. **6** is a rear view showing a preferred configuration of the detector and alarm module of the embodiment shown in FIG. **4**.

FIG. **7** is an electrical schematic diagram showing one preferred circuit for implementing the present invention.

FIG. **8** is an electrical schematic diagram showing an alternate circuit for implementing the invention.

FIG. **9** is a perspective view illustrating a preferred method of releasably fixing the third, capacitively coupled, embodiment of the invention to a diaper.

FIG. **10** illustrates the removal of the embodiment of FIG. **9** from a soiled diaper for reuse on a new diaper.

FIG. 11 is an electronic schematic showing a preferred circuit for implementing the third, capacitively coupled, embodiment of the invention.

FIG. 12 is a front plan view of the button-shaped housing for the third embodiment of the present invention.

FIG. 13 is a rear plan view of the third embodiment showing the interleaved fingers of the capacitor detector.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in more detail to the drawings, in which like numerals refer to like parts throughout the several views, FIG. 1 illustrates a wet diaper detector assembly **10** that embodies principles of the invention in one preferred form. The assembly **10** is shown partially exploded to reveal clearly the elements of the invention with the preferred placement of the assembly on a diaper **11** being illustrated in phantom lines.

The detector assembly **10** comprises an elongated strip of material **15**, which has first and second ends **16** and **17** respectively. The strip **15** preferably is formed of a moisture absorbent insulating material and carries a pair of spaced conductors **18** and **19** (FIG. **2**) that extend along the length of the strip **15**. As illustrated in FIG. **2**, the strip **15** is provided with an adhesive backing **20** that is normally protected by a peel-off strip **21**. In use, the peel-off strip **21** is removed just prior to attaching the assembly **10** to a diaper so that the strip **15** can be adhered securely within the diaper extending through the crotch area thereof as illustrated in phantom lines in FIG. **1**.

A generally rectangular flexible band **23** carries the electronic detector and alarm circuitry of the invention and is adapted to be positioned on the exterior of a diaper **11** at the upper front or rear portion **14** thereof. In use, the band **23** is releasably secured to the diaper by means of a rectangular adhesive patch **39** that is slightly larger than the band **23** and that is applied over the band to cover and protect it and to secure it releasably to the diaper's exterior surface.

As best illustrated in FIG. **3**, the flexible band **23** preferably is fabricated from two rectangular strips **28** and **29** of flexible material between which is sandwiched the miniaturized electronic components **30** of the invention. During assembly, the rectangular strips **28** and **29** are adhesively and permanently joined to form a unitary assembly such that the electronic components become sealed and protected between the strips **28** and **29**.

The electronic components **30** and their configuration are discussed in detail hereinbelow. In general, however, these components comprise a power source in the form of a small thin watch battery **31** that powers a detector circuit **32** and an audible alarm **35**, which, in the preferred embodiment, comprises a miniaturized melody source of the type commonly embedded within greeting cards and the like. A pair of spaced electrical contacts **33** and **34** are positioned in the mid-portion of the band **23** and are coupled to the detector **32**. The detector **32** is configured to monitor the electrical resistance between the contacts **33** and **34** and to activate the alarm **35** when such resistance falls below a pre-established value.

The exterior surface of rectangular strip **29** carries a pair of spaced spiked or barbed conductive guides **24** and **25** positioned to overly and make electrical contact with the contacts **33** and **34** when the strips **28** and **29** are sandwiched together. The guides **24** and **25** are configured to receive and position the protruding end **16** of strip **15** at the mid-portion of band **23** as illustrated in FIG. **1**. The spikes or barbs **26** penetrate the strip and make electrical contact between each of the guides **24** and **25** and a respective one of the conductors **18**, **19** of the strip **15**. It will thus be clear that, with the wet diaper detector thus assembled, the detector circuit monitors the electrical resistance between the spaced conductors of the strip **15**.

When using the embodiment of FIGS. **1–3** for detecting and signaling a wet diaper condition, the elongated conductor bearing strip **15** is adhesively secured within a diaper extending through the crotch area thereof with one end **16** of the strip protruding from within the diaper at the upper edge **14** thereof. The detector band **23** is then pressed onto the strip end **16** with each conductor of the strip overlying a respective one of the barbed guides **24** and **25**. The pressing of the strip end and band together causes the barbs **26** to penetrate the strip to establish reliable electrical contact between the guides **24** and **25** and the conductors **18** and **19**.

With the strip end and band pressed together, the strip is folded over the top edge of the diaper to position the detector band on the outside of the diaper of the upper front or rear portion thereof as shown in phantom lines in FIG. **1**. The band **23** and strip end **16** are then securely but releasably affixed to the diaper by means of the adhesive backed patch **39**, which is sized to overly and cover the band to protect it from food, moisture, and unwanted tampering.

With the assembly **10** thus installed, the diaper is placed on an infant in the usual way and the detector circuit begins to monitor the resistance between the conductors **18** and **19** within the diaper. The pre-established resistance threshold value is selected such that the monitored resistance between the conductor is above the threshold when the diaper is dry but falls below the threshold when the diaper and the strip therein become wet. Accordingly, when the infant wets its diaper, the resulting resistance drop is detected by the detector, which, in turn, activates the alarm to alert a parent or attendant to the wet diaper condition. When the soiled diaper is changed, the detector band **23** is removed from the diaper and decoupled from the strip end **16** for reuse on a fresh diaper. The used conductor strip **15**, which is inexpensive and thus expendable, is simply discarded with the soiled diaper.

FIGS. **4–6** illustrate a second or alternate embodiment **40** of the present invention. This embodiment is also configured for use with an ordinary diaper **41** that has front and rear portions **42** and **44** and an inner intermediate portion **45**. The assembly **40** comprises an inverted T-shaped flexible strip **46** having an elongated first leg **48** and a second leg **49**, which preferably extends normal to the first leg **48** (FIGS. **1** and **2**). Extending along the length of the first leg **48** is a pair of spaced conductors **50** and **51**, that terminate in respective contacts **53** and **54** at the intersection of the legs of the T-shaped strip **46**.

Preferably, adhesive backings **55** and **56** are provided on the second leg **49** of the T-shaped strip **46** for purposes detailed below and the backings are normally protected by peel-off strips (not shown). Adhesive backing and a peel-off strip also is provided along the back side of leg **48** so that this leg can be secured within the interior of the diaper as detailed below. An adhesive backing **58** (FIG. **5**) can also be provided on the back of the T-shaped strip **46** at the intersection of its legs for securing the wet diaper detector assembly **40** onto the exterior surface of the diaper **41** as illustrated in phantom lines in FIG. **4**.

As illustrated in FIG. **6**, a detector and alarm circuit is encased within a thin plastic housing **60** having a front side

61 (FIG. 4) and a rear side 62. A pair of spaced electrical contacts 64 and 65 are located on the rear side 62 of the housing 60 and are electrically coupled to the detector circuit within the housing, as discussed below and as illustrated in FIGS. 7 and 8.

The housing 60 encloses the miniaturized electrical circuitry that, as in the first embodiment, monitors the electrical resistance between the contacts 64 and 65 and activates the alarm when such resistance falls below a pre-established threshold value. The contacts 64 and 65 are spaced to overlay and make electrical contact with the contacts 53 and 54 on the T-shaped strip 46 when the housing 60 is pressed into position at the intersection of the legs of the strip as best seen in FIG. 4. It will be apparent that with the housing 60 thus positioned, the detector monitors the electrical resistance between the spaced conductive strips 50 and 51 that extend along leg 48 and activates the alarm when such resistance falls below the pre-established threshold value.

The wet diaper detector assembly 40 is shown in phantom lines in FIG. 4 as it appears when installed on a diaper 41 for use. When installing the assembly, the T-shaped strip 46 is first affixed to the outside rear or front portion 44 of the diaper by means of the adhesive backing 58 on the back side of the strip 46. The second leg 48 of the strip 40 is then folded over the top edge of and into the interior of the diaper, where it is adhesively secured in position extending through the crotch area of the diaper (FIG. 4). Thus, the conductive strips 50 and 51 are exposed within the diaper at its crotch portion, which tends to be the portion most susceptible to wetness.

With the first leg 48 of the T-shaped strip positioned in the diaper as shown at 70, the detector housing 60 is positioned at the intersection of the legs of the T-shaped strip with each of its contacts 64 and 65 engaging a respective one of the contacts 53 and 54 thus coupling the detector to the conductors 50 and 51. The protective peel-off strips are then removed from the adhesive backing 55 and 56 and the second leg 49 of the strip 46 is folded up and over the housing 60 and adhesively secured to the exterior of the diaper on either side of the housing. The housing 60 is thus securely captured and held in place by the folded and secured second leg 49 of the T-shaped strip 46 as illustrated in FIG. 4. With the detector assembly 40 thus secured, the diaper can be fitted to an infant or toddler in the normal way.

When the diaper 41 is fitted to the infant, the resistance between the two metal strips 50 and 51 normally remains above a threshold as long as the interior portion 45 of the diaper 41 is dry. However, when the infant wets his diaper, thus wetting the first leg 48 of the T-shaped strip 46 at 70, the resulting moisture causes the resistance between the conductors 50 and 51 to fall below the threshold level. The detector circuit detects this reduction in resistance and activates the alarm, which preferably emits a pleasant melody, to alert an adult or an attendant of the wet diaper condition. The wet diaper can then be changed, whereupon the detector housing 60 is removed for reuse while the used T-shaped strip 46 is discarded along with the soiled diaper.

FIG. 7 is an electronic schematic diagram illustrating a preferred circuit for implementing the present invention. In this embodiment, the spaced conductors 75, which normally are positioned on the strip within a diaper, are formed of dissimilar metals such as, for example, silver and copper. In this way, when acidic urine contacts the conductors the urine functions as an electrolyte and the conductors and urine become a battery that supplies power for operation of the circuit.

As the conductors 75 become charged upon contact with urine, they provide current to charge capacitor 74. When capacitor 74 becomes sufficiently charged, the electrical potential across the capacitor functions to "turn on" transistor Q1, which, in turn, conducts sufficient current through R1 and through voltage divider pair R2 and R3 to turn on transistor Q2. With transistor Q2 in its on or conducting state, power is supplied to the alarm MS, causing the alarm to emit an audible alert signal. Preferably, the alert signal is a pleasing melody that will not upset an infant but that will be sufficiently noticeable to alert a parent or guardian to the presence of wetness within the diaper. In some instances, sufficient current is supplied by the urine battery for continuous operation of the alarm. However, in some instances, the generated current is not sufficient and the alarm is sounded intermittently as the capacitor 74 charges and discharges.

FIG. 8 is an electronic schematic diagram illustrating another embodiment of a detector and alarm circuit for implementing the present invention. In this embodiment, the circuit is powered by an auxiliary battery 79. In operation, the electrical resistance between conductors 80 falls when the conductors are contacted with urine or other wetness in the diaper. In turn, current is conducted through resistor R5 and R1. The resulting voltage drop across resistor R5 turns transistor Q1 on, which, in turn, turns on transistor Q2 as with the embodiment of FIG. 7. With transistor Q2 in its on or conducting configuration, power is supplied to the alarm MS, which emits an audible signal to alert the attendant of the wet condition of the diaper. With this embodiment, the audible alarm sounds continuously until the wet diaper is changed since continuous power is supplied by the battery 69.

FIGS. 9–13 illustrate another preferred embodiment of the present invention wherein wetness within the diaper is detected through capacitive rather than resistive coupling. In this embodiment, there are no strips or conductors that extend into the interior portion of the diaper. Rather, the detector and alarm circuit is contained in a button-shaped housing that is fixed completely on the exterior of the diaper.

Referring to FIGS. 9 and 10, the diaper 111 is seen to have a back side 112 and a front side 113. While the illustrated diaper is of common disposable construction, it will be obvious that this embodiment of the invention might well be used with virtually any type of infant diaper. As best seen in FIG. 9, the detector and alarm circuitry in this embodiment is contained within a button-shaped housing 114 having a front surface 116 and a rear surface 117 (FIG. 10). The front surface 116 of the housing 114 is provided with a small central opening 118 through which the audible signal-produced when a diaper is wet is emitted. The rear surface 117 of the housing is provided with a pair of electrical conductors 119 and 121 (best seen in FIG. 13). The conductors 119 and 121 are formed with mutually interleaved fingers that together define what is essentially a parallel plate capacitor. Thus, the conductor 119 is capacitively coupled to the conductor 121, as more fully described below.

The detector and alarm circuit of this embodiment of the invention preferably is removably fixed to the front surface or crotch area of a diaper 111 by means of an adhesive patch 122. The patch 122 has a peel-away backing (not shown) that can be removed to expose adhesive on the back surface of the patch. The adhesive patch 122 is formed with a generally key-shaped tear-away tab 123. The tab 123 has a circular bulb portion 124, which is positioned approximately in the center of the patch 122 and is slightly larger in diameter than the detector and alarm housing 114. The tab

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123 is also formed with a finger 126 that extends upwardly beyond the top edge of the patch 122. It will be understood that the back side of the patch 122 is provided with adhesive in all regions except the region defined by the tab 123 so that the tab itself does not stick to the surface of the diaper when the patch is adhered to the diaper.

In use, the peel-away backing is removed from the adhesive patch 122 and the patch is secured to the outside surface of the diaper as shown in FIG. 9 with the detector and alarm housing 114 sandwiched between the patch 122 and the surface of the diaper and positioned behind the bulb portion 124 of the tear-away tab 123. For this purpose, the bulb portion 124 of the tab is provided with a cut-out opening 127 through which the audible signal emitted from the detector can be emitted.

With the housing 114 thus fixed to the surface of the diaper, it will be understood that the rear surface 117 and capacitively coupled conductors 119 and 121 are held firmly against the outside surface of the diaper. As described in more detail below, when the interior of the diaper is dry, the conductors are only weakly capacitively coupled. However, when the diaper becomes wet inside, the moisture within the diaper acts as an electrolyte that increases the capacitive coupling between the conductors 119 and 121. This increased capacitive coupling is sensed by the circuit of this embodiment and an audible alarm is triggered in response thereto to alert a parent that its infant's diaper has been wet. As shown in FIG. 10, when the wet diaper is changed, the finger 126 of the tab 123 is grasped firmly and the tear-away tab 123 is pulled downwardly away from the patch 122 as indicated by the arrow in FIG. 10. This allows the detector housing 114 to be removed from the diaper so that it can be applied to a new dry diaper for continued wetness monitoring. Thus, this embodiment of the invention not only eliminates the need for interior conductors in the diaper, it is also easily removed and reused many times with only the inexpensive patch 122 being discarded with each use.

FIG. 11 illustrates a preferred electronic circuit for implementing the capacitively coupled embodiment of the present invention. In this embodiment, an oscillator 128 is configured to provide an oscillating voltage signal at its output. In the preferred embodiment, the oscillator 128 comprises an electronic timer chip, such as a Model 555 or 551 chip, that is configured to oscillate at a predetermined frequency to provide a generally square wave output. There are many other circuits that could be configured to provide an oscillating signal for use in the present invention. However, the configured timer chip of the illustrated embodiment is considered preferable because it is inexpensive and easily configured. However, this should not be considered to be a limitation of the present invention since any other means of producing an oscillating voltage signal would function equally well in the present invention. Whatever the configuration of the oscillator 128, it is essential that it produce an oscillating voltage signal such as that illustrated at reference numeral 129 in FIG. 11.

As discussed above, the capacitive sensor 121, which is disposed on the rear surface of the housing 114, comprises a first conductor 119 and a second conductor 121. The conductors 119 and 121 are configured to have interleaving fingers 131 and 132. This configuration of the conductors 119 and 129 creates what essentially is a parallel plate capacitor so that the conductor 119 is capacitively coupled to the conductor 121. Thus, when the oscillating voltage signal 129 is applied to the conductor 119, the signal is capacitively transmitted to the conductor 121 with an efficiency that depends upon the spacing between the fingers and the dielectric properties of the medium in the region of the fingers. At any rate, some portion of the signal 129 is capacitively transmitted to the conductor 121 and this transmitted signal is represented by number 133 in FIG. 11.

The capacitively transmitted signal 133 is fed to the input of a first operational amplifier (op. amp.) 134, which is configured as a simple signal amplifier. The amplified signal present at the output of op. amp. 134 is rectified and smoothed by means of a diode 136 in conjunction with a capacitor 137 to produce a DC voltage that is proportional in value to the amplitude of the signal 133 transmitted through the sensor 120. Thus, when more of the signal 129 is transmitted through the sensor, the DC voltage at junction 138 decreases proportionally.

The DC voltage at junction 138 is fed to the input of a second op. amp. 139, which, in this instance, is configured as a simple comparator. The DC voltage at 138 is compared by op. amp. 139 to a pre-established threshold voltage that is determined by the values of resistors 141 and 142 and capacitor 143. As long as the DC voltage at 138 remains above the threshold voltage, the output of op. amp. 139 is high. However, if the DC voltage at 138 rises below the established threshold voltage, the output of op. amp. 139 goes low. Finally, the output of op. amp. 139 is coupled to a beeper 144 in such a way that when the output of op. amp. 139 goes low, the beeper 144 is activated to sound an audible alarm.

The just described circuit functions as follows. The sensor 120 is held firmly against the exterior surface of a diaper in a region of the diaper subject to wetness. As long as the diaper is dry, the capacitive coupling between the conductors 119 and 121 is relatively small so that a relatively small portion of the signal 129 is transmitted through the sensor 120. However, when the diaper becomes wet, the urine in the diaper functions as an electrolyte which increases the efficiency of capacitive coupling between the conductor 119 and 121. As a result, more of the signal 129 is capacitively transmitted through the sensor 120 and the amplitude of the transmitted signal 133 increases. This increased amplitude signal is amplified by op. amp. 134 and rectified by diode 136 and capacitor 137 so that the DC voltage present at 138 decreases in proportion to the increased amplitude of signal 133. In practice, the values of resistors 141 and 142 and capacitor 143 are selected to establish a threshold voltage that is between a typical DC voltage at 138 when the diaper is dry and a typical DC voltage at 138 when the diaper is wet. Thus, when the voltage at 138 increases as a result of a wet diaper, the threshold voltage of op. amp. 139 is exceeded. This causes the output of op. amp. 139 to go low which, in turn, activates the audible beeper 144 to alert a mother that its baby's diaper has become wet. The wet diaper can then be changed and the housing 114 removed and used on a new diaper as discussed above.

FIGS. 12 and 13 show a preferred embodiment of the front and rear surfaces of the detector housing 114 respectively. As can be seen, the front surface 116 of the housing is provided with an opening 118, through which the audible beep signal is transmitted when a diaper is wet. The rear surface 117 of the housing 114 carries the conductors 119 and 121 with their interleaved fingers 131 and 132 positioned as shown. While the particular configurations shown in FIGS. 12 and 13 are preferred, it will be understood that such configurations are not a requirement nor a limitation but are only shown as exemplary configurations.

The invention has been disclosed and described herein in terms of preferred configurations and methodologies. How-

ever, it will be obvious to those of skill in the art that numerous variations of the illustrated embodiments could be implemented within the scope of the invention. For example, the audible alarm of the preferred embodiments might easily be replaced with a visual indicator, such as a flashing LED, or even a small transmitter for transmitting a radio signal to a remote receiver when the diaper becomes wet. Further, a wide variety of simple electronics in addition to those illustrated might be implemented to perform the same functions in an acceptable way. These and other additions, deletions, and modifications might well be made to the exemplary embodiments illustrated herein without departing from the spirit and scope of the invention as set forth in the claims.

I claim:

1. An apparatus for use with a diaper to detect the occurrence of a wet condition in the diaper and produce an alarm signal in response to such detection, said apparatus comprising:

a housing having a front surface and a rear surface and being sized to contain electronic components and to be affixed to the exterior surface of a diaper with said rear surface of said housing positioned against the diaper's exterior surface;

capacitive sensor means located on said rear surface of said housing, said sensor means having a first conductor capacitively coupled to a second conductor, said capacitive sensor means being configured and positioned on said housing rear surface to be positioned against the exterior surface of the diaper when said housing is affixed to the diaper with no portion of said capacitive sensor means extending into the interior of the diaper;

circuit means in said housing for monitoring the electrical capacitance between said first conductor and said second conductor of said capacitive sensor means;

means for producing an electrical signal when the electrical capacitance between said first conductor and said second conductor meets a pre-established criteria;

means responsive to said electrical signal for producing an alarm; and

means for removably affixing said housing to the exterior surface of the diaper with said capacitive sensor means held against the diaper,

whereby the capacitance between the first and second conductors increases as a result of the dielectric effects of a wetted diaper and the increased capacitance triggers an alarm indicative of a wet diaper condition.

2. The apparatus of claim 1 and wherein said housing is generally button-shaped.

3. The apparatus of claim 1 and wherein said capacitive sensor means is carried on said rear surface of said housing so that it is held firmly against the exterior surface of a diaper when the housing is affixed to the diaper.

4. The apparatus of claim 3 and wherein said first and second conductors of said capacitive sensor means are configured with mutually interleaved fingers to define a parallel plate capacitor configuration.

5. The apparatus of claim 1 and wherein said circuit means comprises means for producing an oscillating voltage signal and applying such signal to said first conductor of said capacitive sensor means, means coupled to said second conductor for detecting the amplitude of the voltage signal capacitively transmitted from said first conductor to said second conductor, means for comparing the detected amplitude to a pre-established threshold amplitude, and means for producing an alarm when the detected amplitude exceeds the pre-established threshold amplitude.

6. The apparatus of claim 1 and wherein said means for removably fixing said housing to the surface of the diaper comprises an adhesive flap sized to be adhered to the diaper with said housing sandwiched between said flap and said diaper.

7. The apparatus of claim 6 and wherein said adhesive flap is formed with a tear-away tab positioned such that said housing can be located in a region of said tab when said housing is sandwiched between said flap and the diaper.

8. The apparatus of claim 1 and wherein said housing is non-adhesively affixed to said diaper.

9. The apparatus of claim 1 and wherein said housing is disposed on an outer surface of said diaper.

10. An apparatus for use with a diaper to detect the occurrence of a wet condition in the diaper and produce an alarm signal in response to such detection, said apparatus comprising:

a housing having a front surface and a rear surface and being sized to contain electronic components and to be affixed to a surface of a diaper;

capacitive sensor means located on said housing and having a first conductor capacitively coupled to a second conductor;

circuit means in said housing for monitoring the electrical capacitance between said first conductor and said second conductor of said capacitive sensor means;

means for producing an electrical signal when the electrical capacitance between said first conductor and said second conductor meets a pre-established criteria;

means responsive to said electrical signal for producing an alarm;

means for removably affixing said housing to the surface of the diaper;

said means for removably fixing said housing to the surface of the diaper comprising an adhesive flap sized to be adhered to the diaper with said housing sandwiched between said flap and said diaper;

said adhesive flap being formed with a tear-away tab positioned such that said housing can be located in a region of said tab when said housing is sandwiched between said flap and the diaper;

said tab having a bulbous portion in the center of said flap and an elongated portion extending outwardly from said bulbous portion toward the edge of said flap, said bulbous portion having a size corresponding to the size of said housing and said housing being located within the bulbous portion when fixed to the diaper,

whereby said housing can be removably fixed to the outside surface of a diaper by means of said flap and changing capacitance between the first and second conductors triggers an alarm indicative of a wet diaper condition.

11. The apparatus of claim 10 and wherein said bulbous portion is provided with an opening through which an audible alarm signal can be transmitted from said housing.

12. The apparatus of claim 11 and wherein said elongated portion of said tab extends beyond an edge of said flap to provide a finger that can be grasped to tear the tab away from the flap and thus remove said housing from the diaper for future use.

13. The apparatus of claim 12 and wherein adhesive is provided on the back of said flap only in regions outside of the region defined by said flap.

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